Human Resource Planning and Development in Biotechnology Businesses is an Industry Study. It covers biotechnology basics, biotechnology business operations and a global review of biotechnology Industry. The Skill sets for biotechnology businesses, job specifications and job descriptions along with various HR practices are described in detail.The study focuses on 20 top biotech companies in Health Care, Agriculture and Industrial.It is useful for students and teachers of Biotechnology Management and industry professionals as a ready reference.

Prakash Deshpande

Dr.Prakash Deshpande Ph.D.Biotechnology HRM from Pune University.M.Sc.(Nuclear Physics)M.P.M. Pune University,India.Professor and Director at Leading Business Schools.Management Consultant,Training and OD.Has worked with DRDO,Tata Motors and many more.Effects of Technology on Organizations is Research Interest.Visits to Singapore, UK etc.

978-3-659-41019-2

HRP and D in Biotechnology Businesses

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Impressum / Imprint
Bibliografische Information der Deutschen Nationalbibliothek: Die Deutsche Nationalbibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über http://dnb.d-nb.de abrufbar.

Bibliographic information published by the Deutsche Nationalbibliothek: The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available in the Internet at http://dnb.d-nb.de.

Coverbild / Cover image: www.ingimage.com

Verlag / Publisher:
LAP LAMBERT Academic Publishing
ist ein Imprint der / is a trademark of
OmniScriptum GmbH & Co. KG
Heinrich-Böcking-Str. 6-8, 66121 Saarbrücken, Deutschland / Germany
Email: info@lap-publishing.com

Herstellung: siehe letzte Seite /
Printed at: see last page
ISBN: 978-3-659-41019-2

Zugl. / Approved by: Pune University, 2006, Pune

TABLE OF CONTENTS

Chapter VI: Demand for and Supply of HR – in Selected Biotech Companies

Chapter VII : HR Planning and Development Processes –An Analysis using Factors

Chapter VIII : Summary of Findings and Conclusions

APPENDICES

List of Tables

List of Figures and Exhibits

List of Figures and Exhibits…continued

ACKNOWLEDGEMENT

I am deeply indebted to many for their support, help, guidance and well wishes and I express my heartfelt gratitude for the same. Though it will not be possible to mention about all of them, I cannot resist mentioning about few of them.

My research guide Prof. Dr. S. V. Kadvekar, a real support and a source of inspiration, encouraged me to undertake the in-depth study of this complex multidisciplinary topic. Dr Kadvekar with his rich academic competence, deep clairvoyance and immense experience, guided me throughout my doctoral thesis work. His constant guidance, support and encouragement have undoubtedly made this Herculean task look simpler and easier to complete. His guidance was especially useful to develop necessary insights into this complex topic and evolve very appropriate format for presentation of this multidisciplinary Industry Study.

Prof. Dr Ashok Kolaskar, former Vice Chancellor Pune University, indicated the scope of the domain and difficulties with appropriate guidelines for overcoming them. Prof. Dr. Chandrashekhar Chitale HOD, Department of Management Sciences, and Prof. Dr. Pandit Vidyasagar, Biophysics, both from Pune University, provided guidance for selection of proper topic through discussions.

Dr Avinash N. Bhisey, former Director, Cancer Research, Tata Memorial, Mumbai, helped clarify the issue of biotechnology techniques usage in India vis-a-vis those used in leading countries.

Prof. J.K. Pal HOD, Prof. V.N.Gade, from the Department of Biotechnology, University of Pune, provided exposure to some of the experimental method aspects of biotechnology, available with the department, for which I thank them both.

Dr. Ashok Ranade, Reader, Institute of Management and Entrepreneurship Development, Bharati Vidyapeeth, Pune, helped me gather momentum for the research process, and shared his views about many aspects of the work through several meetings and discussions.

Prof. S.B. Gogate, former Joint Director, Indian Institute of Education Pune, took interest in perusing drafts proposal and extended valuable suggestions right from the beginning.

I am thankful to Dr. Sharad Gore, Reader Statistics, Pune University, for his advice and facilitation for effective use of IT and statistical analysis. I thank Mr. Rohit Tikhe a Company Secretary and C.A. who earnestly provided help with financial data and analysis.

I thank the staff of Jayakar Library, Pune University, Library at National Institute of Bank Management Pune, the British Library Pune and the library at Institute of Management and Entrepreneurship Development Bharati Vidyapeeth (Deemed University) for their prompt and efficient assistance.

I thank Mrs. Sathe V. V. of Ph.D. section of Pune University for support in all administrative matters.

I thank Mr. Prasad Shaligram and the staff of the Department of Management Sciences, University of Pune for their cooperation.

The support which I received from Human Resource Managers and Senior Managers of various biotechnology companies in Pune, Mumbai, Bangalore and other places, was very commendable. In spite of the pressures, non-availability of ready information, they made time available for clarification of the details and provided maximum inputs for the enquiry to the best of their knowledge and capacity. I am really grateful to them all.

Dr. Anil Thakoor, Supervisor, Bio-Inspired Technologies and Systems Group, Jet Propulsion Laboratory, California Institute of Technology, Pasadena, California 91109, when requested, enthused me by offering to review the final draft and made valuable suggestions which helped improve the quality of presentation to a great extent.

My wife Dr. Savita provided inspiration for this project and it would have been impossible to complete this thesis without her constant support.

Finally, I thank all those who have directly or indirectly helped me complete this thesis successfully.

April, 2006 (Prakash Deshpande)

List of Abbreviations

The abbreviations have been explained while they appear for the first time in most of the cases and those which appear repeatedly have been listed and explained here for the convenience of the reader

ABLE: Association of Biotechnology Led Enterprises

AC: Air Conditioning

AIBA: All India Biotechnology Association

APIDC: Andhra Pradesh Industrial Development Corporation

BCIL: Biotech Consortium India Limited

BHRC: Biotechnology Human Resource Council (Canada)

BIO: Biotechnology Industry Organization (US)

Biotech: Biotechnology

BT: Biotechnology

CAD: Computer Aided Design

CBT: Center for Biochemical Technology

CCMB: Center for Cellular & Molecular biology

cGMP: Current Good Manufacturing Practices

CIP & SIP: Cleaning-In-Place & Sterilization-Place

CRC: Contract Research Company

Crs.: Crores

CSIR: Council of Scientific and Industrial Research

DBT: Department of Biotechnology

DGCI: Drug Controller General of India

DNA: Deoxyribonucleic acid

DSIR: Department of Scientific and Industrial Research

DST: Department of Science and Technology

ELISA: Enzyme-linked immunoassay

FDA: Food and Drug Administration (US)

FPLC: Fast Protein Liquid Chromatography

GCP: Good Clinical Practices

GEAC: Genetic Engineering Approval Committee

GLP: Good Laboratory Practices

GM crops: Genetically Modified crops

GM: Genetically Modified

GMP: Good Manufacturing Practices

HPLC: High Pressure Liquid Chromatography

HRD: Human Resource Development

HRM: Human Resource Management

HRP: Human Resource Planning

HVAC: Heating Ventilation & Air Conditioning

ICAR: Indian Council of Agricultural Research

ICMR: Indian Council of Medical Research

IMTECH: Institute for Microbial Technology

INR: Indian Rupees

IPR: Intellectual Property Right

IT: Information Technology

MAbs: Monoclonal Antibodies

mRNA: Messenger RNA

NAD/NADH: Nicotinamide Adenine Dinucleotide / NAD+Hydrogen

NCCS: National Center for Cell Science

NCBS: National Center for Biological Sciences

NCL: National Chemical Laboratory

NGOs: Non Governmental Organizations

NII: National Institute of Immunology

NMR: Nuclear Magnetic Resonance

OSHA: Occupational Safety & Health Administration

PCT: Patent Cooperation Treaty

QA: Quality Assurance

rDNA: Recombinant DNA

RIA: Radioimmunoassay

RNA: Ribonucleic acid

SIP: Sterilization in Place

SOP: Standard Operating Procedure

TDF: Technology Development Funds

TRIPS: Trade-Related Aspects of Intellectual Property RightS

UDCT: University Department of Chemical Technology

UGC: University Grants Commission

UK: United Kingdom

US: United States of America

USD: US Dollars

UV: Ultra Violet

WTO: World Trade Organization

Chapter I

Introduction

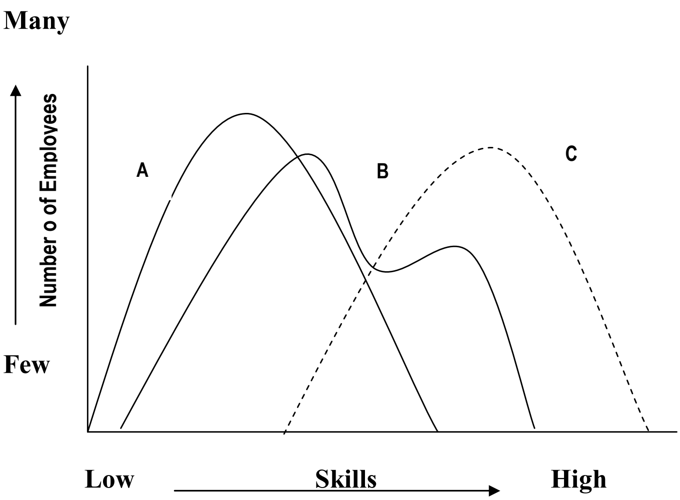
Business is one of the major institutions through which new form of science and technology is introduced into society. Television was introduced by mass communication technology and computers were introduced through process automation and Internet communication. This way, information technology has huge impact on human life and a new wave of literacy to remove the "digital divide" which exists with the explosion of Information technology, is in operation.

After Information Technology, Biotechnology and Genetic Engineering have taken the lead. It has started affecting the quality of life in many ways as this technology is used in Agriculture, Healthcare, Industrial processes and Environmental engineering. Biotechnology business is that field of business which concentrates on newest discoveries in microorganisms and genetics. This is also termed as "Genetic Engineering" when it is specially used for modifying species in a desired and suitable way. An innovative business system can translate scientific and technological developments into useful goods and services for people at large. Looking at the biotechnology in a general way, it is noticed that it has influenced the language and phrases used in the business and they are dominated by the technological jargon while describing the business activities and the skill sets used.

The most fundamental economic effect of technology is greater productivity in terms of both quality and quantity. Therefore new technologies are used strategically for carrying out business expansion projects, cost reduction programs, process improvement programs etc. The developed economies like U.S. faced with emerging competition, make

make large investments in new technologies just for the survival of the technologies and subsequent growth.

With the advances in technology, as has been witnessed in the case of Information Technology, jobs become more intellectual and otherwise upgraded. The changes in the skill distribution of a business required by advances in technology may be qualitatively represented and captured as shown in the fig. 1.1 Skill Distributions.



A=Former Skill Distribution **B**= Intermediate Skill Distribution

C= R & D Skill Distribution

Fig. 1.1 Skill Distributions

Business curve **A** showing former skill distribution was shaped like normal curve of intelligence among people in the old time. Being matched to people, it suggested that an adequate supply of workforce would be available at all levels of business in the long term.

In modern business the curve has moved towards the right, higher in skill as shown in Curve **B** intermediate skill distribution. In many

organizations the skill distribution has become bimodal, as shown in curve **B**. Many scientific and professional people are required in research, development, planning and other specialized jobs creating secondary bulge or mode towards skill end of the scale.

Curve **C,** R & D skill distribution represents skill distribution that is developing in business firms oriented towards R & D. Even though these firms manufacture products for sale, much of their efforts are devoted to research for development and to building a small number of complex products for maintaining competitive edge in the market. In these firms the number of scientists, technologists, and applied engineering experts exceeds the total number of other employees.

The increased number of intellectual workers represented by curve **B** and **C** has placed new challenges and responsibilities on management of businesses. It is this new responsibility of managing the creative spirit, which is sometimes called "Maverick Management" (Maverick is a person who takes bold steps).

1) Historically, scientists have worked in small laboratories at their own pace, usually in an academic setting but lately they have started working more and more for big organizations both in private and public sector. Most certainly they perform best in a work culture different from that of assembly line.

2) Creative and intellectual workers expect relatively high job freedom. They are motivated by opportunities that offer change, growth and achievement.

3) They are less motivated by expectations of higher formal authority than by their professional interest and perceptions of opportunities.

4) Their orientation is cosmopolitan towards their profession and the world outside their organization rather than local, depending primarily on reward structure of the firm itself.

5) Although they are a part of the company work culture, they are just as much part of a separate scientific culture operating beyond their organizational boundaries.

Under these conditions summarized in few points, they may have organizational restlessness that tends to increase job mobility.

Businesses are adjusting their supervisory practices to meet needs of intellectual workers. Some companies have established dual promotion ladders so that distinguished technical people can rise to ranks and receive salaries that are equivalent to those of managers. Flexible work schedules are allowed. Profit sharing is provided to give creative persons a financial stake in the ideas they create and to discharge their restlessness. Attendance at professional meetings and writing professional articles and similar activities are supported. In further response to intellectual workers cosmopolitan interests they are allowed and encouraged to teach part time or are given special assignments.

Scientific and other specialized workers make up the techno structure of modern organization and exert much influence on decision making processes. According to J. K. Galbraith "the techno structure embraces all who bring specialized knowledge, talent or experience to group decision making. This, not the management is the guiding intelligence—the brain—of the enterprise"[1] (John K Galbraith, The New Industrial State, Boston: Houghton-Mifflin, 1967 p.71). Since the majority within the techno structure of most organizations is likely to be scientifically and technically trained persons, and care must be taken to assure that they do not become a technical elite dominating business and social decisions. They are experts concerning the technical feasibility of

the product or process. Their expertise in the area cannot be questioned, so they may become impatient with people who stand in the way of technically feasible project. However, their expertise may be the factor that limits their broader view of social effects. Business managers therefore have a responsibility to assess pluralistic views within the firm, as well as view points from stakeholder groups outside the firm, when making decisions concerning technology. As technology has advanced, R & D becomes a giant new activity. It has become so important that it is ranked along with production and marketing. This creates a special need for human resource with specialized talent and skills capable of handling the outcomes of the R & D activity. Since this human resource brings revenue as well as social benefits through increased productivity, the effective management of human resource viz. management of specialized human skills and talent becomes highly important.

In order to operate these new forms of businesses driven by symbiotic combination of latest technologies – like emerging biotechnology, (which is a symbiotic combination of molecular biology, biochemistry, advanced genetic engineering and information technology etc. - please see chapter II for more explanation) human resource management faces new challenges.

It is against this background that the study of Human Resource Planning and Development in biotechnology businesses has been undertaken.

Human Resource Planning and Development is a process that identifies current and future human resources needs of an organization to achieve organizational goals. Human Resource Planning and Development is a process that links people management to the organization's vision, mission, goals and objectives as well as with organizations strategic plans and budgetary resources. The goal of this process is to get the right number

of people with the right skills, education, competencies and experience in right jobs at right time at right cost.

The main aspects required to be considered in charting the process of human resource planning and development are as under:

i) Business process and objectives of the organization

ii) Capacities and capabilities of the organization's current work force or human resources needs. The skills and competencies required.

iii) Estimates of supply of and demand for human resource as employees.

iv) Appropriate plan for development of employees towards work performance currently as well as keeping in mind the changes envisaged in business process and operations.

It is therefore most logical in present study to begin with knowledge and understanding of origin and growth of biotechnology, identification and classification of biotechnology businesses, specialized aspects of biotechnology business development, products and processes, typical job positions available in biotech businesses, in the context of technology and management. In organizations of present times the primary assets of business are the talents, skills and competencies of its people, not the tangible and financial assets which are presented in the balance sheets. Biotechnology business organizations are no exception to this. In view of the changes in skill distribution and job content, human resources have an edge over other resources.

1.1 The Study

Like every **"Industry Study"** the present study is also an exercise in scientific method, which consists of a combination of induction and deduction.

Change in technology brings about a change in job content. With the emergence of biotechnology, there is a change in job content, as a result of which new combination of inputs have taken place. This change in job content has a natural impact on the human aspect of the business, more specifically on human resource management functions of any business where the business is technology driven. This is the reason why it was thought fit to select the human resource area and more particularly the 'Human resource planning and development' for present study. The human resource planning and development process needs to be evaluated against the backdrop of following factors

A) An overview of Biotechnology Business:

B) The Organization of Operations and HRM functions in Biotech Business:

C) Human Resource Scenario in Biotechnology Business:

The details of these factors set forth for the study, are:

A) An overview of Biotechnology Business: Technology basics, Identification, classification of biotech business, Origin and growth, Global Scenario, Major countries with sectorial focus, their contribution in terms of revenue, employment status, India's place in global scenario and strategic focus.

B) The Organization of Operations and HRM Functions in Biotech Business: typical biotech business model, Bio-manufacturing capacity, Technical Processes, Resources, Products, and Stage wise changes in functions, related changes in size and type of workforce. Bio-science technical specialist's characteristics, Organizational design.

C) Human Resource Scenario in Biotechnology Business:

(i) **Knowledge, Skill Sets Required in Biotechnology Business**: Theoretical framework of HRM, HRP and HRD. Typical Job Positions available, Typical Task description, Typical Technical and Managerial Skill Sets required, Job Description and Job Specifications.

(ii) Revenue Creation and Human Resource Employed, Business Models, Products and Processes. Status of Human **Resource Planning and Development Process in Biotechnology Business Organizations.**

1.2 Objectives of the Study

The specific objectives of the research, against the backdrop of discussion above, have been formulated and they are as under-

1. To Trace the Origin and Growth of Biotechnology Businesses and to gain understanding of Biotech Sector in terms of Technology Basics, Main Applications, and Extent of Global Spread with Revenue and Employment Generation.
2. To understand the Organizational Development of Typical Biotechnology Industry in terms of the different Skill Sets and Tasks required for Biotech Business Process.
3. To review Theoretical Aspects of HRM as required for developing proper perspective for studying HRP and D for Biotech Businesses.
4. To gain understanding of Knowledge and Skills requirement of Typical Job Positions available in Biotech Organization, with Job Descriptions and Job Specifications and explore experiences from other countries in similar HR issues.

5. To Review and to Analyze Human Resource Planning and Development Process in selected Biotech Businesses.
6. To Suggest ways and means for Improving activities of Human Resource Planning and Development in Biotech Businesses.

Thus the study is both empirical as well as analytical. The development of biotechnology businesses in India is comparatively new and upcoming phenomenon. The business sector itself is very cautious in responding to the same. However, considering the global character of biotechnology, this sector has become a 'high value' business proposition. The central government in India and various state governments have included biotechnology in their priority list along with information technology. As has been mentioned earlier, technology considered being a single factor responsible for changes in skill distribution, and the same is true in the case of biotechnology. This technological scenario poses a challenge to the business managers while managing the necessary human resource i.e. Planning, Recruiting, Developing Organization and Teams for achieving business goals, Retaining Recruited employees and while conducting Training and Development activities.

The 'people first' syndrome therefore makes biotechnology business sector unique. An attempt has been made to explore this in the present study.

1.3 Research Questions

It is customary to formulate hypothetical statements (after literature review), and devise a method to test the hypothetical statements for the topic under study. These are also stated along with the objectives of the study. When the study is of exploratory nature with descriptive methodology, research questions are also appropriate substitute to hypotheses. It is more so for the dynamic and fast changing technology

industry which is in its initial stages in India, and all sectors of the same have yet to take roots even on global level. This is the reason why researcher has chosen to spell out the research questions rather than forming hypothetical statements, and the research questions are stated as under:

1. What are the peculiarities of Biotechnology Business sector in terms of Resources, Products, Business Operations, and Organization?
2. What are the Constraints on this Industry in terms of Availability of Right type of Workforce?
3. What are the different aspects relating to Demand for and Supply of HR in Biotech sector?
4. What is the scenario of Human Resource Planning and Development Processes followed in Indian Biotech Business? Do they require any New Initiatives?

1.4 Methodology

The main purpose of this section is to describe the thought and procedure followed for adopting the method used for the study under its context. It is divided into four parts: I) Research Design, II) Primary and Secondary sources, III) Collection of Data and IV) Selection of the Sample.

I) Research Design: The research design selection is generally an outcome of the literature review; the researcher has carried out literature review with following purpose:

a) To Make an attempt to satisfy the Objectives of the study in general
b) To Make and attempt to answer the Research Questions and
c) To identify the proper platform for the Research Design.

The design of this study fundamentally belongs to exploratory research design. The study in its first phase has undergone an extensive literature review of the concerned subject matter, which is one of the methods of exploratory research. The secondary sources of information are very important for exploratory research. For the present study the secondary sources have provided information of fundamental nature which is very basic to the process of organization of biotech business. The changing need of HR in different stages of business, the global picture in terms of scope and spread of biotechnology business and its economic importance, employment generation and present strategic directions in which it is being driven globally was obtained through secondary sources of information. For understanding of human resource planning and development issues for biotech businesses, this information provided foundation.

In addition to questionnaire survey, case study method was also employed. The experience survey i.e. collection of responses by means of questions or schedule and interaction with the HR and other senior managers who have practical experience in the field of HRP and D of biotechnology business was undertaken so as to collect information for tabulation and analysis in aggregate, which could be used along with knowledge gained from case studies, for drawing inferences and making suggestions. The questionnaire is pertaining to the human resource planning and development and was tested by researcher for validity and reliability by trying it out with few senior managers of pilot group of companies and sorting out ambiguities. This process also validated the contents in terms of skill sets and other aspects related to biotech HRP and D. This process suits the present study because it relates to formulating a problem as well as going for more precise investigation and developing working questions from an operational point of view.

The present scenario of Indian biotech businesses is characterized by the following features:-

1. Indian biotech businesses are in their infant stage when compared with global biotech businesses
2. The processes are complex and subject to rapid changes because of advent in technology in different areas of biotech such as tissue culture, healthcare, monoclonal antibodies, industrial and environmental. They fall into broad categories viz. Agriculture, Healthcare, and Industrial etc., as described earlier.
3. The manpower requirements and related issues are not yet very satisfactorily addressed because of lack of information and experimental phase of the businesses.
4. Need for creation of awareness and facilities for developing human resource from the viewpoint of technical as well as managerial capabilities and skill sets.

In such circumstances exploratory design is suitable which is also required for developing a process for study while stimulating insights.

From the above description, the reader would appreciate that considering the circumstances of the study, the design tools and techniques selected by the researcher are most appropriate one. Thus as a conclusion, the study pertains to exploratory design with slight incorporation of descriptive design characteristics as regards the procedure of the study.

II) Primary and Secondary Sources: The primary sources of information are the senior managers in the biotech companies and interaction with them for the purpose of case studies and questionnaire survey. As has been mentioned in the research design part, the secondary sources helped for providing the foundation for exploration of Human Resource issues at micro level. The secondary sources are mainly,

published business reports by international agencies, websites of Biotechnology Industry Organization, USA, Literature and surveys published by Biotech Human Resource Council, Canada, Regional organizations from UK, Government of India circulars and documents for the purpose of policy and strategy, Directory of BCIL and Publications of ABLE biospectrum for the purpose of information about universe and sample for the study and various regulatory and other related business issues in the context of Human Resources for biotech businesses. The primary and secondary sources have been cited and listed in the bibliography in this study.

III) Collection of Data: The focus for data collection becomes clear by stating the topic of study in terms of problem statements, which are as follows

a) What is the nature of biotech business and what are its distinguishing features?

b) What are the typical technical processes affecting resources and tasks in this business?

c) What is specific human resource knowledge and skill sets requirements for performing the tasks in biotech business?

d) What is the HR scenario for biotech businesses in terms of human resource planning and development?

It is important to remember here that for any business the HR issues such as Planning and Development require a foundation of other resources and their organization for successful business operations. As the development of biotechnology businesses is relatively a recent phenomenon in the world, the data and information necessary to build overview and foundation necessary for understanding of HR issues was collected from the secondary sources mentioned above. This provided the macro level data. Micro level data for case studies and questionnaire

survey, from primary sources such as senior managers from the biotechnology companies was collected through personal discussions, telephonic and email communication and administration of the questionnaire.

IV) Selection of the Sample: A list of 20 companies with their revenue in Rs. Crores, which provided a reasonably representative and purposive sample for the present study as discussed below.

Considering the requirements of the study it was decided to select these 20 companies with higher turnover, as a sample. The efforts were focusing on proper no. of companies which would have substantial HRP and D environment in those companies.

Table 1.1 List of 20 Companies Selected as Sample, with Revenue & Sector.

No.	Sector*	Company name	Revenue**
1	1,3	Biocon	502.00
2	1	Serum Institute of India	491.00
3	1	Panacea Biotech	149.00
4	1	Nicholas Piramal	130.00
5	1	Novo Nordisk	110.00
6	1	Venkateshwara Hatcheries	88.00
7	1	Wockhardt	84.00
8	1, 2	GlaxoSmithcline	80.00
9	1	Bharat Serums & Vaccines	79.68
10	1	Eli Lili & Co.	67.40
11	1	Novozymes	65.00
12	1	Quintiles Spectral	62.55
13	1	Krebs Biochemicals	56.88
14	1	Indian Immunologicals	56.70
15	1	Zydus Cadila	55.00
16	2	Mahyco Monsanto	54.00
17	1	Shantha Biotechnics	40.00
18	1	Syngene Internationals	38.48
19	1	Biological E	38.37
20	1	Span Diagnostics	36.62

*1:BioPharma, 2:Agriculture 3: Industrial, **Revenue in Rs. Crore. F.Y. 2003-04

If these companies are selected as sample the consideration was how much they will represent the population (not on the overall basis but from the view point of magnitude of the HRP and D in true sense, which was the requirement of the study). According to BCIL directory[2] there are in all 328 companies registered as biotech companies and out of which 30 % are in bio Pharma or healthcare business, 30 % in agricultural biotechnology and rest 40% are in various different biotech supporting businesses including industrial biotechnology etc. The companies selected as sample are listed in table 1.1 before the discussion is taken further.

These exercises lead the researcher to an assumption that, magnitude of HRP and D activities should be based on revenue generation of the companies. It is obvious that the companies would have the employees and related HRP and D activities shall commensurate with the revenue generation of the company.

Thus the researcher found it suitable to look into the revenue generation of companies, as HRP and D activities shall vary in proportion to the revenue generation. As it has been proven in chapter V, *fig. 5.5 Business class and percentage share in revenue* that top 20 companies have 59% of share and thus the selection of these top 20 companies would give a representative sample on revenue generation basis. Another supporting fact is that as proven by *fig. 5.4 Percentage Sales revenue-for each sector*, that bio Pharma has 55% share in revenue, and as seen from Table 1.1, that all 20 companies are from bio Pharma except one which is in agriculture biotech sector.

Thus the contention of selecting a small number but a representative, purposive sample shall be agreed by the reader when he will appreciate it on the basis of the background described by the foregoing lines.

Case Study Method: As the case study was used as a complimentary tool for overall understanding of biotechnology business, it

includes information such as, company history, major departments and their activities, awards and recognitions received by the company if any, future challenges. Observations analysis and inferences about business processes and HRP and D activities for drawing inferences are also included.

1.5 Scope and Limitations

The study relates to Human Resource Planning and Development which consisted of analysis of forecasting of demand for and supply of HR and HR Planning and Development as a process at macro and micro levels. However, this required knowledge and understanding of skills in demand. This in turn depended on organization of biotech business operations. It was required to be studied in the context as application of biotechnology is international in character.

The study therefore covers the following aspects:

1) Identification of Skill Sets related to Biotechnology Business Operations.

2) Forecasting Analysis of Demand for and Supply of Human Resources for Biotechnology Business

3) Examination of Factors or Parameters influencing sound Human Resource Plan and

4) Identification of Education and Training needs both Technical and Managerial for Entry Level and Senior Candidates

Limitations: This being an **'Industry Study'** with a focus on HR Planning and Development, the same is conditioned by operational trends noticed in this industry. As regards research methodology and sources of data and information, certain constraints cropped in. Therefore the study cannot be said to be without any limitation. The main limitations are described below:

(1) As a reflection of global scenario, the concentration in Indian biotech business at present times is in bio-pharmaceuticals, though industries in other sectors are present and emerging. Since the significant development has taken place in Bio-Pharma, description of operational aspects is mainly focused on bio-manufacturing and drug manufacturing. In the sample selected for the study however, companies from agricultural biotech are also covered.

(2) In view of availability of large stock of knowledge and information about biotechnology businesses across various sources including print media, electronic media etc. secondary sources were used freely, for verifying and properly identifying the research questions, stages of growth of biotech business etc.

Secondary sources are not without problems. The data available may not be timely; the same may have bias and different purpose. Due care has been taken while using data.

(3) As the Biotech Industry in India is in nascent stage of development, the companies which have ventured into this sector are primarily preoccupied with establishing the setup for sustaining and for maximizing marketing for being competitive in the globalized economy. All these industrial and business parameters force the HR issues to adequacy level and researcher found that this was a major limitation for invoking interest of the corporate HR and other senior managers for getting involved with this type of academic study, which is otherwise a dear subject to them.

(4) On the government policy level, though many state governments had their biotechnology polices announced by 2000-2001, 'The Indian National Biotech Policy–draft' was just released in 2005, and at the government level there were no substantial initiatives taken to translate the policy draft into action plans. This naturally results into a climate of

uncertainty for biotech business. This further limits their business plans.

Biotech business professionals and business managers seem to be rather in a state of ambiguity about harnessing support from policy makers while devising their own strategic business plans. This subsequently affected their response while sharing their experiences with the researcher.

Of course the researcher was successful in invoking cooperation of the concerned individuals from different biotechnology companies selected for the study.

1.6 Conclusion

Biotechnology organizations, whether they are research oriented, government departments, private sector or may be a suitable combination of them - have one common need. They require human resource/workforce with wide range of skills to take and translate the valuable scientific and technological data into useful information, products and services for the purpose of commercialization.

This study has explored data and information of fundamental nature which is necessary for developing an understanding of operations of biotech business with a focus on Human Resource Planning and Development issues. Human Resource Management requires specific planning and allocation of resources in a way that will be new and difficult because the techniques and resources of this technology are relatively new to Indian players. This fundamental information includes basics and continuous development of biotechnology, different techniques in practice, overview of global scenario, operational aspects, education and skill set requirement of this business, external factors, etc. The field study of the selected biotech units provides indicators for status of Human Resource Planning, Training and Development. With this it was possible to view the relative difference between the global and Indian biotech scenario from

Human Resource Planning and Development point of view for making an attempt of drawing inferences and making suggestions.

This exercise may be labeled as one in the area of “Knowledge Management” and has put forth following new points as contribution to the existing knowledge

1. Biotech business has global spread, rapid growth and it is important from business development and higher productivity point of view as a diversification strategy.

2. In a technology driven business such as biotechnology, skill distribution has become bi-modal, the scientists representing creative spirits and business managers representing business spirit. Therefore this calls for a unique and challenging situation for Human Resource Management. More specifically, effective HR Planning and Activities of Training and Development are necessary as there is need for bringing the technology and leadership together.

3. The Indian biotech business is in early and infant stage of development and therefore faces some problems and difficulties such as

i) Lack of proper vision and business strategies from HR Planning and Development point of view on policy front. (As reflected by non availability of systematic information about Knowledge, Skills and Competencies required.)

ii) Neglect towards important HR management activities including HR Planning, Training and Development by Nodal Agencies.

Chapter II has presented an overview of biotech business which has prepared a foundation and backdrop on which the HR issues are developed for understanding of different variables in the context of the present study.

ENDNOTES

[1] John K Galbraith, The New Industrial State, Boston: Houghton-Mifflin, 1967 p.71

[2] Directory of Biotechnology Industries and Institutions in India, 4th edition, 2004 Biotech Consortium India Ltd. New Delhi.

Chapter II

Biotechnology in Business – An Overview

2.0 Introduction

The background of the study has been explained in the chapter I. In this chapter, an overview of Biotechnology Business is presented. This is necessary because for India this technology is new and the overview will provide the present global spread of this technology and its socio economic impact. This will also show the relative position of Asia Pacific region where biotech is emerging and India is a part of the Asia Pacific region.

While presenting overview it was felt that, it is necessary to deal with basics of scientific aspects of biotechnology. This will help clarify the issues of definition of biotechnology and biotechnology business, identification and classification of the same in different sectors and the growth pattern and products in this business. So as to achieve this, the presentation in this chapter has been structured as follows.

In the beginning, basics of scientific aspects of biotechnology and main applications of biotechnology are considered. This made it possible for the researcher to throw light on the definition and identification aspects and special features of biotechnology and biotech business. With the range of applications, it was easier to identify the sector of the business. After this, historical review of growth and spread of biotech business on global level has been described. This laid the foundation necessary for understanding of the resources, processes essential for building operational aspects. This subsequently is necessary for understanding the HR issues in the context of Human Resource Planning and Human Resource Development for biotechnology businesses.

2.1 Biotechnology - Scientific Basics

Biotechnology is different than other technologies. The most important feature of this technology is the raw material and the processes used. Biotechnology uses animal and/or plant cells and microorganisms as raw material. Their natural life processes are made use of for harnessing new useful products and services in the domain of agriculture, human and animal health care, industrial processes and combination of the various domains. The description and review of biotechnology per say, is beyond the scope of the present study, however it is interesting as well as essential to know in brief, about types of living organisms, about molecular basis of life, DNA and chromosomes, RNA and flow of genetic information, replication of DNA, microorganisms and use of their life processes for making useful products and providing services. This will also make the point of impact of technology on the job content clear to some extent and more will be discussed during description and review of operational aspects of the typical biotech business.

A pictorial review is presented as Evolution of Life – Varieties of Living Organisms. – Just as an illustration, before molecular basis of life is described.

Fig. 2.1 Evolution of Life -Varieties of Living Organisms has been presented on the next page as it is necessary for it to have a full page space.

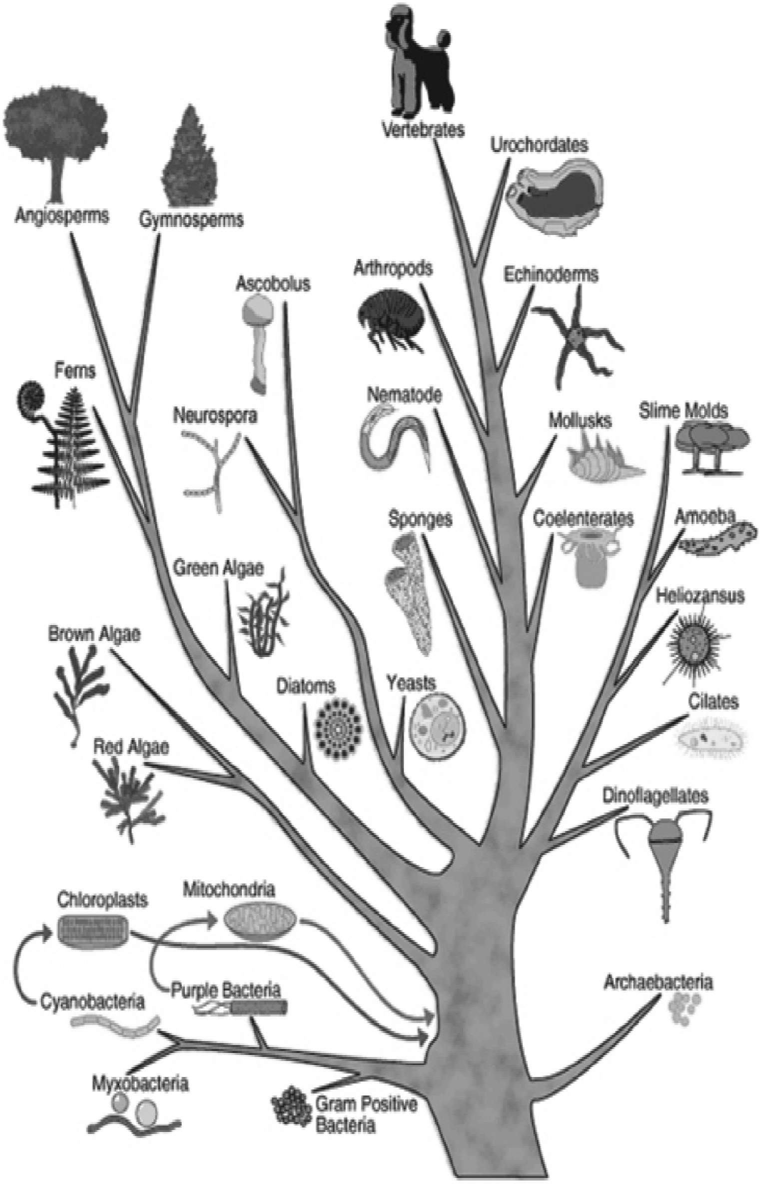


Fig. 2.1 Evolution of Life -Varieties of Living Organisms

2.1.1 Molecular Basis of Life[1]

Understanding the molecular basis of life is very basic to understanding of biotechnology. Salient features of molecular basis of life are explained below in simple language with the help of fig 2.2

- Basic units of all living organisms are tiny cells.
- When viewed under the magnifying devices like microscopes, most of the cells have a darker staining body called nucleus. Nucleus is surrounded with the viscous fluid cytoplasm, and is enveloped by a semi permeable cell membrane.

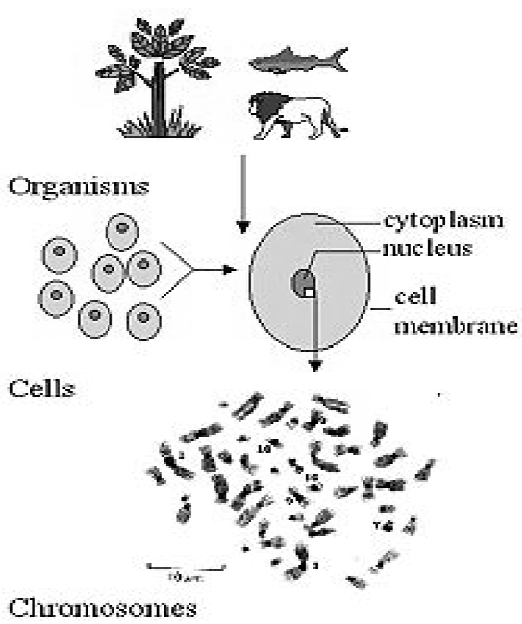


Fig. 2.2 Molecular Basis of Life

- Inside the nucleus, the genetic material DNA (DeoxyriboNucleic Acid) is present, which **at the time of cell division** assembles into the higher order structure called chromosome.

- In a human cell, the entire genetic material is bundled into 23 pairs of chromosomes, and is collectively referred as the 'human genome'. Figure 2.3 graphically depicts DNA and chromosomes

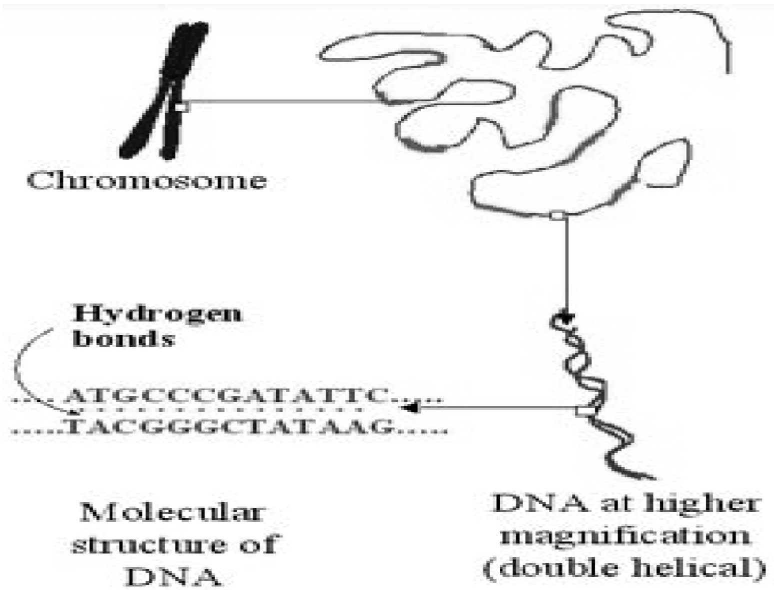


Fig. 2.3 DNA and Chromosomes

- The DNA, present in each of the chromosomes, is one very large double stranded molecule, present in the double helical form.
- Genes are the short stretches of DNA, on the large total DNA molecule, that encode for RNA (Ribonucleic acid) and proteins
- In each strand of the DNA, the basic units, deoxy-ribonucleotides, are joined together by a 5'-3' phosphodiester linkage.
- The two strands of DNA are held together by the hydrogen bonds, formed between them.

Flow of genetic information is shown in figure 2.4

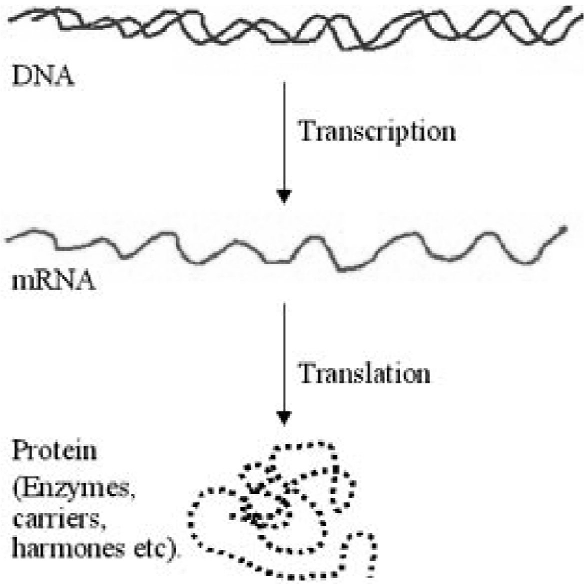


Fig. 2.4 Flow of Genetic Information

- The flow of genetic information includes the transcription of gene into a mRNA (messenger RNA) molecule that undergoes translation to form proteins.
- If a gene from one organism is transferred to another organism, it will encode its protein product at the new destination also.
- An alteration in the gene will result a change in the encoded protein. This is the **basis of differences** amongst different individuals.
- Some alterations may lead to the formation of aberrant proteins or no protein at all, leading to different genetic diseases.

This clarity is essential for the understanding of definition of biotechnology and its applications which are described below.

"Biotechnology" refers to the use of living organisms to develop products.

Some description of how a biotech process which is a symbiotic combination of various technical processes from diverse disciplines makes production of useful products is now understood.

With the use of new scientific discoveries, it is possible to understand the fundamental life processes at the cellular and molecular level. It is possible to improve selected attributes of microbes, plants, or animals for human use, by making precise genetic changes that were not possible using traditional methods. How that happens has been explained briefly in the following lines.

It takes either a single self-sufficient cell or several types of cells living together to make a complex living organism. These cells of all living organisms contain genes. Genes are the carriers of the hereditary traits between descending generations. Genes can be compared with videotape for the purpose of understanding. Both DNA and videotape are long, linear strings of information. This information is encoded in a particular way- the genes encoded with DNA and the tape encoded with magnetic particles or domains. Both the tape and the genes can be copied (*cloned*), or edited (*recombined*). Tape is relatively stable, while DNA is quite dynamic. A tape cannot replicate itself while DNA can. This has been graphically represented in Fig 2.5 DNA replicating itself[2]

In nature, genes are continuously modified, and DNA is commonly transferred within and between species. It is interesting to note that traditional breeding involved random mixtures of many genes, while modern biotechnology allows a single gene from a strand of thousand genes, to be isolated and changed. *It is interesting to know that the end products of biotechnology such as corn syrup or soybean oil are merely products of gene action; they do not contain any genes.*

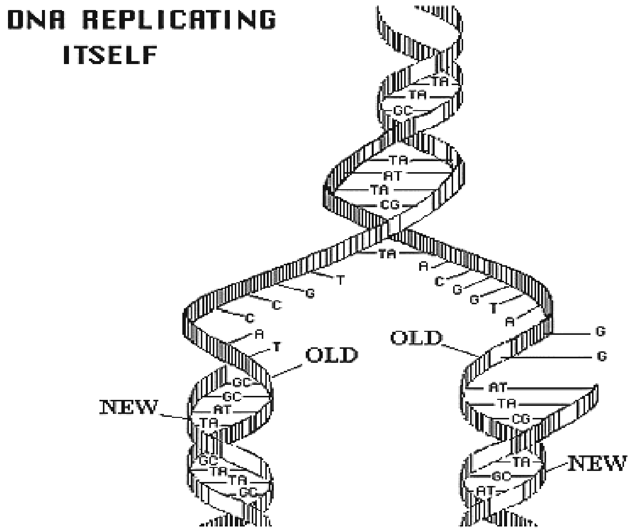


Fig. 2.5 DNA Replicating Itself

When we eat any food, whether obtained from traditional or modern biotechnology sources, it is broken down into simple compounds such as amino acids or fats that are readily digested by our systems.

2.2 Main Applications of Modern Biotechnology

Biotechnology has applications in many fields. There are some main applications and others are derived from them for various purposes, for improving quality of human life. The main applications are described in the context of the present study.

2.2.1 Microbes: Microbes (for example yeast for making curds, cheese, or making bread, or bacterial flora in our intestine) are a part of our everyday life and environment. Functionality of key food ingredients such as enzymes can be improved with the help of microbes. Enzyme for making cheese is now improved through biotechnology. Other uses include improved types of yeasts for bread, better bacteria for yogurt, and new therapies to fight food-borne diseases. Enzymes used in detergents and pollution removal are made using genetically modified microbes.

2.2.2 Plants: With the help of biotechnology, plants can be made to have disease resistant characteristic. Nutritional value of crops can be enhanced, for example, rice enhanced with 'vitamin A'. It will prevent childhood blindness and / or with iron to reduce the occurrence of anemia. It will also be possible to remove undesirable substances such as saturated fats or substances responsible for allergic reactions from food. *With modern biotechnology, scientists can add or remove small pieces of genetic information in a very precise manner, with precise end results in mind which was not possible before.* **So precision and predictability are characteristics features of biotechnology**

2.2.3 Animals: Pets and domestic animals can be made to have disease resistance characteristics. This is done through the use of improved animal medicines and other methods of disease treatment. Many of these treatments reduce the need for antibiotics, hormones, or other protection tools. It is possible to improve animal feed to ensure better nutrition and reduce the amount of animal waste. Biotechnology has also been used for many years to improve animal breeding, reproduction, and growth.

2.2.4 Humans: Scientists can now determine the genetic factors which contribute to either good health or disease. It will be possible to intervene in a disease at an earlier stage through new medicines. Lifestyle changes, better nutrition, are some of the other uses, which are now possible in a more predictable manner. Diagnostic tests will make it possible to anticipate the development of a disease before it either begins or becomes advanced. This will make it easier to practice prevention.

To summaries this, it can be said that, Biotechnology is not a single technology but it is a collection of Technologies and a symbiotic combination of many technologies. We can break the word into its roots [as has been done by BIO(biotechnology Industry Organization), US,]

Bio- the use of biological processes and

Technology- To solve problems or make useful products

This makes it easier to understand the meaning and scope of the term. *Using biological processes is not a new event. Humans began growing crops and raising animals 10,000 years ago to provide a stable supply of food and clothing. Human beings have used the biological processes of microorganisms for 6,000 years to make useful food products, such as bread and cheese, and to preserve dairy products.* **The difference with biotechnology is that, the change in the biological processes can be engineered precisely, which was not possible without modern biotechnology.**

The reader is requested to refer to the references for more information. (For the growth of biotechnology in terms of timeline, please see appendix III). After this the definition and classification of biotechnology businesses is dealt with.

2.3 Definition and Classification of BT business

"Biotechnology" is not an industrial sector, but rather a set of methods useful in many industrial sectors such as pharmaceuticals and enzymes, industry, agriculture and also for some entirely new applications[3] (e.g., DNA forensics). This is an accepted definition of biotechnology throughout this study.

There are several definitions of biotechnology business as defined and used by various organizations the world over. With some minor differences in wordings, effectively they convey the same meaning. One such elaborate definition made by directorate of industries, government of Maharashtra[4] is quoted briefly below as an example. This is useful as a reference meaning.

2.3.1 Bio-Technology (BT) unit means a unit engaged in Research and Development and/or manufacture of products which use or are derived by using

(a) Living systems, (b) Enzymes

(c) Biocatalysts derived there-from,

The term 'unit' refers to a legal / corporate entity (e.g. a Public or Pvt. Limited Company/Partnership or Proprietorship Firm / Registered Society or Trust/Cooperative Society), or a distinct separate facility at a different location, of such an entity. It could be a company owned by government or private bodies.

2.3.2 Classification of Biotechnology Units:

Generally, Biotechnology units are classified into four groups depending on their focus field, namely

(a) **Healthcare or Bio Pharma:** Human and Animal Health Bio-Tech products and processes unit,

(b) **Agricultural** Biotech products and processes unit,

(c) **Industrial** and other Bio-Tech products and processes unit,

(d) **Composite** Biotech unit undertaking Bio-Tech activities covered under two or more of the above categories.

The organization Biospectrum in India, has classified biotech industry in a different manner, which is also given below.

1. **Bio Pharmaceuticals**
2. **Bio Agriculture**
3. **Bio Industrial**
4. **Bioinformatics and**
5. **BioServices / BioSuppliers.**

Here Bio-Informatics-implies assembly of data from genomic analysis into accessible form, and is a tool for biotechnology with a combination of Information Technology. The meaning of the terms BioServices /Biosupliers is obvious, services for biotech business and supplies for biotechnology businesses (supplying raw material, animals and plants, machinery and instruments, chemicals etc.)

BCIL has a different classification system and that has been referred to when the BCIL data is analyzed as a basis of status of Biotech businesses in India in the context of the present study. ABLE-Biospectrum has evolved another classification system as stated above. These multiple systems of classification do not affect the basics of biotechnology and HRP and D requirements. This situation about variety in classification systems by different organizations is acceptable, as it is emerging one and it is hoped that it will stabilize in due course of time and a classification system acceptable to all players globally, will be in vogue. This is stated so as to avoid confusion which might be created in the minds of the reader because of the different systems of classification adopted by various organizations.

Global scenario of biotech business is presented in the form of a review to the extent it will be useful in the context of the present Biotechnology Industry Study for studying the Human Resource Planning and Development in Biotech Businesses.

2.3 Global Biotech Scenario[5]

Historical review of Global biotech is presented in the following lines. Biotech business the world over represents different sectors [as mentioned above Agriculture, Industrial, and Healthcare (Bio-Pharma) etc.] in which it has emerged and growing. Following salient features in brief, characterize the snapshot of the scenario in the recent history.

According to BIO (Biotechnology Industry Organization) US, the biotechnology industry was born with the founding of '**Genentech' on April 7, 1976. in the US.** From that time the industry has grown from a lone start up to a sector that generates revenues of $ 46 billion in the US. alone. On the cusp of its 30th birthday, in the United States of America, this is an industry that is emerging from the volatility of a teenager - an uncertainty of early adulthood, to the maturity, focus and rationality of an accomplished adult. In the US the sector is providing new therapies for unmet or underserved medical needs, delivering on its promise to improve the quality of life around the world.

According to Ernst and Young "Global biotechnology reports"[6]

1. In 2002 nearly 10% additional employment was generated in the US biotech businesses.
2. The biotech industry, led by the US, rebounded in 2003 and 2004 from the depressed stock market conditions of 2001 and 2002, but the recovery has been uneven across the globe.
3. This rebound is making the global biotechnology industry a major force leading the creation of a new health economy in which **biotech, pharmaceutical, and medical device companies are converging with health care providers**.
4. The number of publicly traded biotech companies declined slightly in 2003 to 611 from 619 in 2002, but these companies earned 17% more in revenues and hired more workers, boosting employment 9%, while reducing R&D spending 16% and improving their net loss by 65%."
5. **Globally, the major biotech businesses exist in US, Canada and UK.**

6. The major driving force in these countries is the healthcare or bio Pharma area and most of the biotech businesses are developed with healthcare initiatives.

2.4.1 U. S. Biotech Industry

- **437,400 *U. S. jobs***. Of these, **150,800** jobs (about 35% of total) were generated directly by biotechnology companies, while the remaining 286,600 jobs (about 65% of total) were generated by companies supplying inputs to the industry, or by companies providing goods and services to biotechnology employees.
- **$47 billion in additional revenues.** Even though the industry as a whole remains unprofitable, biotechnology companies produced revenues of $20 billion. (43% of total) Companies supplying inputs or selling goods and services to biotech employees generated revenues of $27 billion. (57% of total)
- **$11 billion in research & development spending.** This includes research and development conducted by biotechnology firms, but does not include research and development conducted by firms supplying the biotechnology industry with inputs or workers with goods and services.
- **$10 billion in tax revenues,** including federal, state and local taxes. The largest components of the tax revenues were individual income taxes, social security and property taxes, with a little over two-thirds of total taxes going to the federal government.

The analysis also estimated the contributions generated by publicly traded and private companies and by the agricultural biotechnology sector:

- Publicly traded companies generated 305,100 jobs and $32 billion in revenues, while privately traded companies generated

132,300 jobs and $14 billion in revenues, including the contributions of companies supplying inputs to the industry or goods and services to employees.

- Agricultural biotechnology generated 21,900 jobs and about $2.3 billion in revenues, including the contributions of companies supplying inputs to the industry or goods and services to employees."

This explains the scope of biotech companies and the socio-economic implications of the same in the U.S.A. along with the **enormous employment generated by the biotechnology sector.** So as to have a review of global scenario, the review of Canadian, European and Asia Pacific region (of which India is a part) is also presented briefly.

2.4.2 Canadian Biotech Industry[7]

The scenario in the US was described in more details so as to understand different dimensions of this business. The salient features of Canadian business are given below in brief

- 15 products entered Phase III trials (assess safety and efficacy of product with 1000-1500 volunteers) in 2004: 25 compounds entered Phase II, (assess safety and efficacy of product with 100-300 volunteers) and several new products were approved for sale.
- The number of Canadian companies remained virtually unchanged since 2003 at 472—the number of both public companies (82) and private companies (390) increased by one in 2004.
- Public company biotech revenues increased by 21% ($2,091 million), while net losses dropped to 30% ($408 million).

- 56% of Canada's publicly listed biotech companies had less than two years of cash on hand in 2004 (vs. 66% in 2003); just 38% companies have over five years of cash (up slightly from the year previous). Private firms are likely to have less cash than their public counterparts, further increasing pressure toward consolidation in that sector.
- There were four instances of Canadian biotech IPO's (initial public offerings) in 2004.
- The industry remains clustered around Montreal, Toronto and Vancouver.

2.4.3 European Biotech Industry[8]

- Total revenues held steady at € 11billion
- Public company revenues decreased 5% to € 6.2 billion, (excluding revenue of Celltech, which was acquired by UCB during 2004), however, with market capitalization increasing 21% gaining €5.5 billion in value
- The net loss for public companies was €392 million, 19% less than in 2003
- Funds raised by public and private companies increased over 14% compared to 2003 and reached a total of €2.8 billion, making 2004 the European industry's second best funding year ever
- After two years without initial public offerings, 2004 brought nine IPO's raising in total €300 million for European companies – mainly in Germany, Switzerland and the UK

- Mergers and acquisitions increased from 39 in 2003 to 42 in 2004. M & As (Mergers and Acquisitions) involving US and European companies increased from 9 in 2003 to 19 in 2004, a 3% decrease in research and development (R&D) expenses.
- A 7% fall in employees, (excluding UCB's acquisition of Celltech).

2.4.4 Asia Pacific Region -

Asia Pacific is an emerging region for biotech businesses and it can be seen from the contribution of this region as shown in the fig 2.6 to the global revenue generated in this sector (source: Ernst and Young 2002)

Fig. 2.6 Global Region wise Share in Revenue from biotech (2002)

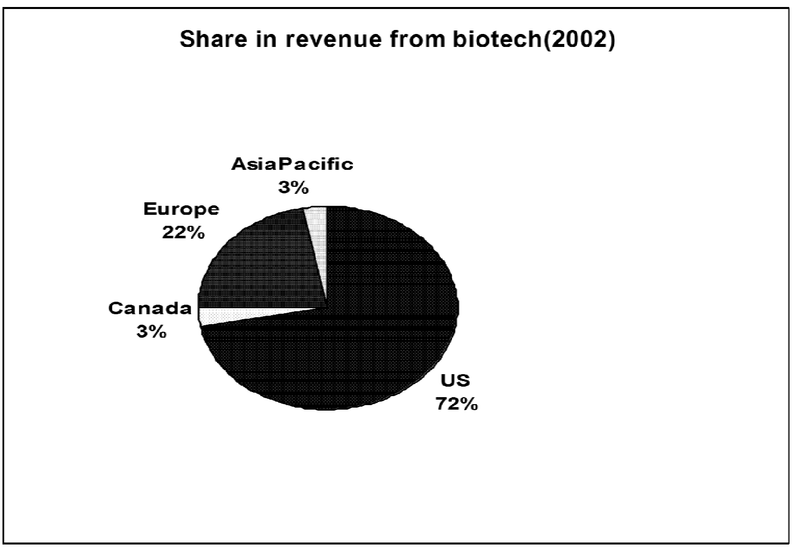
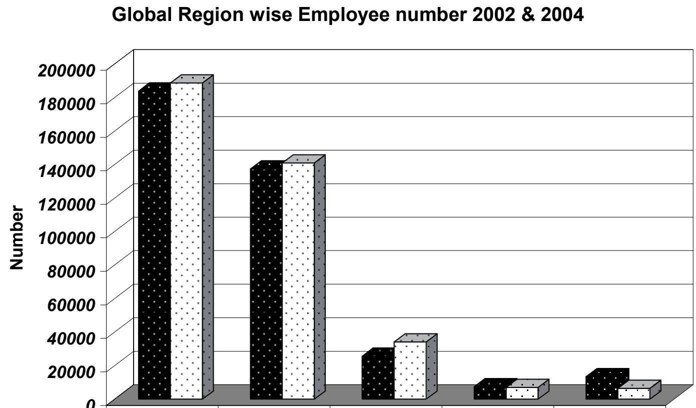


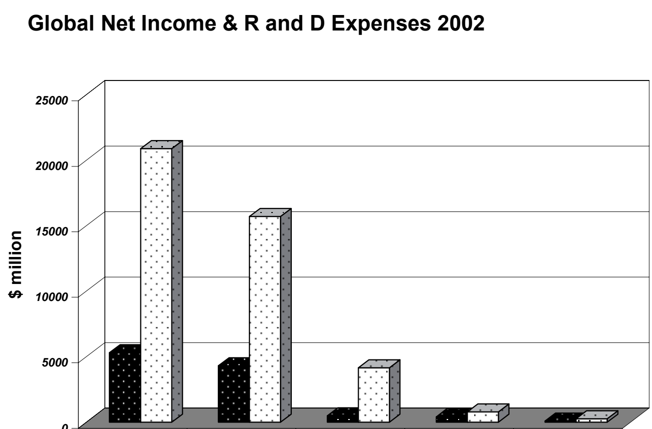
Figure 2.7 shows the region wise employee number for comparison and representing trend of manpower employed.



	Global	U.S.	Europe	Canada	Asia/Pacific
-2004	183820	137400	25640	7370	13410
-2002	188703	141000	34180	7005	6518

Fig. 2.7 Global Region wise Employee number (2002 and 2004)

Figure 2.8 facilitates comparison of these figures region wise against the total global figures.



	Global	U.S.	Europe	Canada	Asia/Pacific
Net Income ($m)	*5304*	*4317*	*484*	*408*	*94*
R & D Expenses ($m)	*20888*	*15701*	*4151*	*782*	*253*

Fig. 2.8 Global Net income and R & D Expenses 2002

Comparison of revenue and number of employees provide information about the emerging nature of biotech businesses in Asia – Pacific region. Comparison of region wise net income and R& D expenses gives information about R & D focus of this business. According to Ernst and Young, China and India are two major players which are in the infant stage and have strategies for growth in the areas of healthcare or Bio-Pharma so as to compete in the globalized market. The inherent advantages of economical infrastructure and cheaper trained manpower India and China have can be cashed by them while generating employment in this emerging sector.

The snapshots of global scenario of biotech business have clarified the issues like who are the leaders, the status and economic impact, employment number in all the major regions of the world. Also the technology intensive and R & D focused nature of this business is brought out by region wise comparison of net income and R & D expenses. This is a useful foundation for developing operational aspects as one can infer that example of healthcare biotech or bio Pharma would be appropriate for developing understanding of resources leading to clarification of operational aspects as well as human resource planning and development issues.

2.5 Conclusion

Details of scientific basics of biotechnology and main applications of biotechnology have been presented in the beginning. With the support of those details the definition and identification aspects and special features of biotech business have been described. With the range of applications, it was easier to identify the sector of the business. The different sectors or categories of business designated by BCIL, ABLE-Bio Spectrum has been noted. After this, historical review of growth and spread of biotech business on global level has been described. The picture

was projected for region wise share of revenue and employment in the biotechnology business. Region wise net income and R & D expenditure comparison showed the R& D focus of biotech business. This has laid the foundation necessary for understanding of the resources, processes required for building operational aspects. This has also suggested that the stage of businesses in Asia Pacific region (India is in Asia Pacific) is infant stage as compared to that of US, Canada and Europe. This is necessary for understanding the Human Resources issues in the context of Human Resource Planning and Development for biotechnology businesses which is the focal aspect of this present industry study.

ENDNOTES

[1] http://www.biotechcitylucknow.org/tutorial.htm

[2] An Insider's Guide to the Biotechnology Industry and its Careers, (http://www.genomeseb.com/)

[3] www.stanford.edu/class/siw198q/websites/genomics/finalrpt.htm

[4] BT/BTU/Registration/(3)/2002/A-7685,H. O. CIRCULAR No - 21/2002 Directorate of Industries, New Administrative Bldg., Opp. Mantralaya, Mumbai-32

[5] http://www.ey.com/global/content.nsf/International/Home

[6] (http://www.ey.com/global/content.nsf/International/Home)

[7] http://www.ey.com/global/content.nsf/Canada/Media_-_2005_-_Biotech_Report

[8] http://www.ey.com/global/content.nsf/UK/Media_-_05_06_01_DC_-_Global_biotech_report_2005

Chapter III

Organization of Business Operations and Human Resource Management

3.0 Introduction

In chapter II, review of biotech businesses in leading countries such as US, Canada, European countries and in the Asia Pacific region has been presented. It may be noted that, some of the situations in terms of external factors may be changing in a positive or negative direction for biotech businesses but the operational aspects in terms of processes, resources, operations and required workforce specification for designing organization, do not differ drastically in different phases of development of technology. The reason for this may be that the processes in the current business structure have stabilized over a period of time and many of them have been become standardized practices. This also means that they are not necessarily location specific. Starting with research, trials, regulatory approvals, manufacturing and sale becomes the common necessity for all working in the biotechnology businesses. The planning and development strategies are adopted taking into consideration the particular biotech product or service. Keeping this in mind it can be said that the organization of biotech business revolves around operations of bio manufacturing, next to initial research and development. Bio Pharma can be considered typical example for the purpose of elaborate description of operations, tasks, knowledge and skill necessary for the same. It was established in the chapter II that Bio-Pharma is leading the world over. Moreover, modern biotechnology operates at molecular level of plant and animal cells & microbes and therefore the operational details would change to the extent of raw material and finished products for other sectors. It is against this backdrop the development of biotechnology industry in terms of

operational aspects is described step by step in the following paragraphs. Later on the organization design is discussed as a process leading to human resource planning and development which are some of the major functions of Human resource management. The theoretical framework of Human Resource Management pertaining to present study has been dealt with in the end of this chapter.

3.1 Biotechnology and Industrial Development[1]

A typical firm may start as a research and development firm employing biotechnology in their research, in the field of agriculture, pharmaceutical, industrial chemicals, and environment and so on.

As the biotechnology research and development firms mature and move into manufacturing and sale of their products, they also become defined not only by the technologies they employ but also by the type of products they make. They become, for example, agricultural or pharmaceutical or chemical companies. The business typically starts with drug discovery for Bio Pharma, and different stages and time span required for them has been shown in table 3.1 Drug Discovery and Development Process.

It is essential to understand that the methods of biotechnology have the potential to impact a variety of established industries - both in research and manufacturing. Biotechnology will play an increasing role in research and manufacturing in the chemical, agricultural and environmental industries. This description also brings out a special feature of biotechnology viz. that **it requires proprietary technology products.**

All the stages explained in the table 3.1, make it clear that the manpower and other resources requirement may be different at various stages of operations and have been discussed in pages which follow. The major step after regulatory approval is manufacturing and the Bio

manufacturing capacity is discussed taking the status of operations at present times in consideration.

Table 3.1 Drug Discovery and Development Process

Year	Stage/Phase	Probability of advancing to next stage
0	**Discovery of a Promising compound. Patent clock begins clicking**	
1-4	**Pre-clinical Testing, Lab and Animal Tests. Investigational New Drug. (IND) application submission**	1/1,000 (0.1%) of the promising compounds result in an investigational New Drug (IND) submission. 85% to Phase I Clinical Trials
4-6	**Phase I Clinical Trials, assess Safety and Metabolism, 30-50 volunteers**	80% to Phase II Clinical Trials
6-8	**Phase II Clinical Trials, Assess Efficacy and Safety, 100-300 volunteers**	28% to Phase III Clinical Trials
8-12	**Phase III Clinical Trials, assess Efficacy and Safety, 1000-5000 volunteers used to Monitor Reactions to Long Term Drug Use**	65% to New Drug Application (NDA) submission
12-14	**New Drug Application** **100,000 pages data reviewed by Federal Drug Administration**	90% of the NDA are approved by FDA
14	**Drug Reaches market. Post-Market evaluation**	
17	**Patent expires**	

Sources: *Association of Clinical Research Professionals /Pharmaceutical Research and manufactures of America.*

3.2 Changes in the Size and Type of Workforce

The topic of the present study requires that the discussion of other resources should be limited to the extent necessary to make the HR issues clear. Therefore stage wise change in size and type of work force is discussed in this section.

As have been stated in table 3.1, it can take up to 14 years to get from an idea in the laboratory to the drug store shelf. *As the process moves from laboratory to manufacturing plant, the size of the workforce grows. At early stages, people with graduates degrees in science are required, when manufacturing begins, more people with only a high school diploma or college education are required.* It has been shown in fig.3.1 Changes in the size and type of workforce.

It should be noted here that as mentioned in the introduction of this chapter that these operational details except for variations in regulatory norms, are not location specific and can serve as guidelines for all.

Fig. 3.1 Changes in the Size and Type of Workforce

R & D Lab Workforce Smaller in number More PhD/MS	$\Rightarrow$	Large-Scale Manufacturing Workforce Large number More HS/Diploma-degrees

Different typical stages of process by which a new drug goes to market are discussed after this. This explanation is necessary for developing understanding of the tasks involved in typical biotech operations. The tasks will lead to job descriptions. Job descriptions make it easier to think of knowledge and skill requirements necessary for achieving success in operations. All this information forms basis for organizational design and human resource planning and development. Therefore the typical stages are briefly described in the following paragraphs.

3.2.1 Research and Development

Drug development begins in the laboratory, while scientists look for compounds that alleviate or prevent disease. This has traditionally involved much trial and error, but the drug discovery process is enhanced by the research tools of biotechnology, which can make the process more targeted and informed by increased understanding of life processes. Many biotechnology companies carry out drug discovery research.

Resources and Work Force: Laboratory equipment and machinery to carry out research in the targeted area. The scale of operations is known as Laboratory scale and Manpower required is scientists, assistants, and laboratory technicians, maintenance and administrative staff etc.

3.2.2 Pilot Scale Manufacturing

A promising drug is then manufactured at pilot scale. For biopharmaceuticals produced by cells grown in culture, this means growing cells in a volume of about 10-200 liters. (Lab scale culture is usually 1-5 liters.) For a traditional pharmaceutical product, this might involve a small-scale chemical synthesis process. At this stage, scientists and engineers are beginning to work out details of what the manufacturing process will be like, and making enough of the drug for initial studies and to use in clinical trials. Some contract manufacturers do this process for their clients who might not have their own facilities.

Resources and Work Force: The scale of operation is increased to 10 to 40 times, as per requirement. The material resources required remain the same though the quantity/scale is increased. It must be noted here that these processes at changed scale involve process engineering so as to keep the quality and quantity of the output within normal acceptable limits. Process engineering results decide the design of pilot plant and machinery and related other resources. So extra manpower required is engineers with knowledge and skills for scaling up and handling the process efficiently

and effectively.

3.2.3 Clinical Trials and New Drug Application Process

This is a process of testing a new drug candidate in volunteer subjects and applying to the authority for approval. **Contract research organizations** also do this for their clients who might not have these facilities at their own establishments.

Resources and Work Force: At this stage the regulatory framework starts becoming more important. The norms of validity of a clinical trial have to be taken into consideration. So this is a part of applied research with consideration of regulatory and ethical norms. This calls for additional knowledge and skill base and manpower which have the necessary knowledge and skills. (Described subsequently in next chapter)

3.2.4 Scale-up to Commercial Production

Scientists and engineers may begin to work out how to scale the manufacturing process up to the eventual desired production volume that will be needed when the drug goes to market. Manufacturing processes sometimes have to be quite different than in the laboratory, or even at pilot scale and scaling-up requires experienced judgment in process or bioprocess development as well as knowledge of scientific and engineering principles. Other resources such as plant and equipment of course need the scaling up with proper design.

The issue of **Resources and Manpower** is clear in the sense that the change in technical process demands new skills and corresponding manpower with necessary education, training and experience. Commercial production involves break-even point and profitable batch size etc. Additional people with techno commercial aspects of production are required along with the other resources.

3.2.5 Large-Scale Manufacturing

At this stage the new drug is ready to go to the market and will need to be manufactured in quantity. This is the stage at which the great majority of employees of pharmaceutical and bio-manufacturing companies work.

The description of each of the blocks in brief will help clarify the functions which in turn will help understand the HRP and D issues.

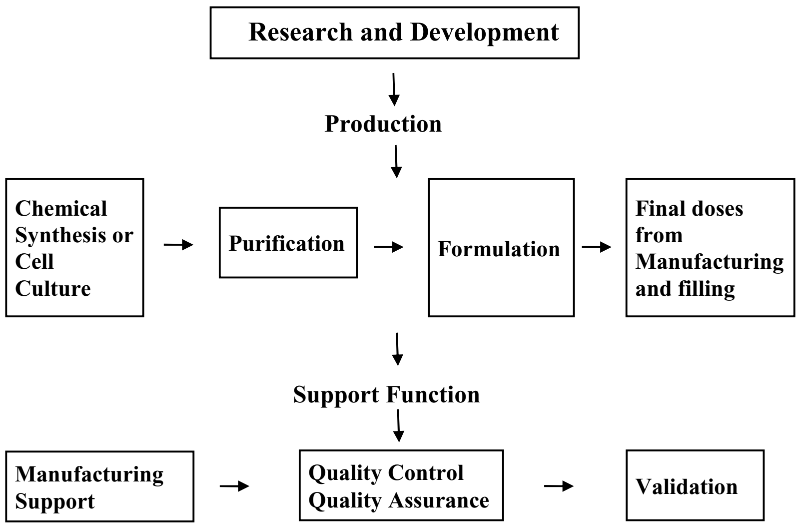


Fig. 3.2 Large Scale Manufacturing

This description is valid for Agricultural biotech or industrial biotech, with applicable changes in the raw material and terminology and applicable regulatory norms. The resources will also have to be suitably changed to match the corresponding process requirements. Having gone through the flow chart for large scale manufacturing, it is easier to understand the functions required for manufacturing which will make clear the human resource requirements for carrying out those functions.

3.3 Manufacturing Functions

The description given below is from the perspective of management, so as to understand the functions. This action is necessary for organizational design and consequent planning of human resources.

A large corporation may have many manufacturing facilities in different locations; (either in the same country or international, as it is suitable for strategic focus within limitations of technical operations) each dedicated to a particular product or set of products, and in some cases to only part of the manufacturing process. However, each product requires the major functions shown in the chart above, whether all the work is completed at one site or multiple sites.

Functions in pharmaceutical or bio manufacturing facility typically fit within the following major divisions. The work in each of these sections is described with typical job titles and educational background needed for the work. While formal departmental organization may differ from one company to another, these divisions capture most of the manufacturing related functions.

3.3.1 Research and Development

Research and Development within a manufacturing context does not refer to the drug discovery type of research and development previously discussed. It refers to research and development as it pertains to the manufacturing processes and product. This could range from developing new assays to test the stability and activity of the product in various stages of manufacturing, to researching a new type of manufacturing technology. This type of work is generally referred to as process development, and it is applied research at the interface between basic research and production. Most employees in this kind of work are engineers and scientists, many with advanced degrees.

3.3.2 Production

Production is the heart of manufacturing. There are many different steps involved in pharmaceutical and bio pharmaceutical manufacturing. The processes involved, particularly for the bio manufacturing industry, are often complex and lengthy operations. To increase clarity about the production function from the management point of view it is described in little more details as it involves processes and steps required in modern biotechnology. This description will help understand the materials and methods from the management point of view. This in turn will make it easier to understand the tasks involved – Task description will lead to job description (tasks can be broken down into achievable jobs by individuals working in a team for achieving the task)

3.3.2.1 Synthesis: the first step involves preparing the materials required for creation of the products. This involves mixing and measuring chemicals and reagents for both pharmaceutical manufacturing and bio manufacturing. In the latter case these ingredients frequently need to be sterilized to avoid introducing contamination. Then the product itself is created, either by chemical synthesis for traditional pharmaceuticals or through cell culture for bio manufacturing.

3.3.2.2 Purification: After the desired product (called the active pharmaceutical ingredient) is synthesized, it has to be purified. That means separating it from the chemicals left over from a chemical synthesis reaction or from living cells and cellular nutrients and byproducts. (Some bio manufacturers purify products from natural sources instead of growing cells in pure culture). The end result of production is called bulk product. This bulk product may be sold as is, processed further at the same plant, or shipped to another plant for further processing.

3.3.2.3 Formulation: Several other operations are required to get the bulk pharmaceutical into final dosage form in which it will be retailed.

Dosage forms can be solid (e.g. tablets or capsules), liquid, gels or creams, or aerosols. Biopharmaceuticals are almost always sold as sterile liquids or sterile dry powders.

Formulation involves chemical mixing operations to blend the active pharmaceutical ingredient with other agents required in the final dosage form, such as granulating agents, fillers, or buffers and stabilizers for adequate shelf life.

3.3.2.4. Final dosage from manufacturing*:* The formulated preparation is put into its final form, for example tablets or sterile solutions, and then dispensed into containers. The containers are labeled and packaged. These kinds of operations typically require the least skilled labor, except for filling of sterile solutions, which requires specially trained technicians.

Manufacturing Process - a Typical Description:

Most production employees work directly with the manufacturing process. They monitor and operate the manufacturing equipment, prepare media and chemicals for the various stages of production, and transfer materials from one operational unit to the next. These workers are usually called process operators (or alternatively manufacturing associates or process technicians). Process engineers make sure the processes are running efficiently, optimize them, and bring new processes to make new products on line.

3.3.3 Manufacturing Support

A variety of other functions support manufacturing. In this division, maintenance of the plant and all its utility systems has been included. Utilities include electrical systems, water purification systems, and heating, ventilation, and air conditioning (HVAC), for example, employees in manufacturing-support groups also maintain the complex equipment

(pumps, valves, piping, and the specialized manufacturing equipment). Process control technicians and engineers design, program and maintain the extensive automated instrumentation and control systems that run the processes.

Another area of manufacturing support is waste management. Employees in this group include technicians with specialized backgrounds in industrial trade, environmental technicians who have some of the same skills as process technicians, and mechanical and electrical engineers.

3.3.4 Quality Control (QC) and Quality Assurance (QA)

Pharmaceutical manufacturing has high standards because the stakes are high. Poor quality products can harm or even kill customers. Companies generally ensure quality through their quality control, quality assurance and validation divisions. While all employees must confirm to the guidelines (Good Manufacturing Practices or GMP) established by the regulatory authorities (like FDA, Federal Drug Administration, in the US), the QC, QA and validation groups have the specific responsibility for making sure that all aspects of a manufacturing process conform to the regulations laid down by the regulatory authority as applicable to that geographical region.

3.3.4.1 The Process of QA and QC - Brief Description

Quality control employees sample and assay both the raw materials and the product during every phase of its manufacture. Quality assurance involves setting up and checking the systems of **Standard Operating Procedures** and **Documentation** that ensure product quality. Much broader than quality control, quality assurance focuses on the overall system of manufacturing. Quality control laboratory technicians usually require college degrees in either chemistry or microbiology. More senior positions can require an MS or PhD degree. Entry-level QC technician positions are a common entry point into the industry for Science graduates.

Quality assurance staff generally must have extensive prior experience in the pharmaceutical industry.

3.3.5 Validation

Validation proves that a standard operating procedure will consistently produce products to described specifications when carried out exactly with specified equipment. **The operation of every part of a plant has to be validated:** manufacturing equipment, utilities, and even the computer data processing systems used to record and document all aspects of production. If the manufacturing process is to be changed, or a new product or process introduced, all steps and parts of the new process have to be validated. Validation scientists and engineers generally need extensive experience in the industry. They must be thoroughly familiar with the regulatory norms and how they are implemented. Thus there are typically few entry-level positions (i.e. those not requiring prior work experience) in these groups.

3.4 Other Divisions

Scientific and technical staff within a pharmaceutical or bio-manufacturing operation may also work in other divisions. Examples of these other divisions are listed below.

3.4.1 Regulatory Affairs: keeping up with regulatory issues that could affect the company (this is outer directed, as opposed to the inner directed activities of QA/Validation)

3.4.2 Information Technology: Setting up, managing and maintaining electronic documentation systems.

3.4.3 Technical Support: Providing expert insights to production staff regarding details of the product or process; troubleshooting problems with the process and/or work on introducing new process.

The pharmaceutical and bio-manufacturing industries also need

scientific and technical employees in the post-manufacturing stages (such as trained sales staff, etc.).

As the current focus of biotech businesses is bio-pharmaceuticals at global level, the description of typical operational requirement is limited to that sector of biotechnology. The common Tasks, Tools, Skills, Knowledge and Attributes of a Bioscience Technical Specialist are described below.

The organizations need human resources for performing the tasks and for finding out the HR requirement (that is demand), is important and necessary prerequisite for HR planning and development function.

If the job functions along with tasks to be carried under that job function are described, it can lead to job description, which is a requirement for deciding job specifications.

3.5 Typical Job Functions and Tasks of a Bioscience Technical Specialist

Typical Job Function and Tasks of a Bioscience Technical Specialist have been described in table 3.2 for the purpose deciding job specifications:

Table 3.2 Job Functions and Tasks of a Bioscience Technical Specialist source: **www.csuchico.edu/csuperb/Skills.pdf**

Bioscience Technical Specialist Performs Experiments and Assays, Manufactures Products, or Assists with Research using a variety of Technical Skills, under supervision					
JOB FUNCTIONS	**TASKS**				
A: **Perform Tests /Assays**	**A-1** Obtain and read protocol, test procedure, SOP	**A-2** Prepare sample for testing	**A-3** Check equipment	**A-4** Determine acceptability and optimum conditions of reagents for tests	**A-5** Assess acceptability /appropriateness of specimen
B: **Manufacture Products**	**B-1** Follow SOP and batch record (protocol or procedure)	**B-2** Obtain raw material	**B-3** Set up equipment according to process requirements	**B-4** Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)	**B-5** Prepare buffers and solutions

C: Obtain Specimen of Materials	**C-1** Request tests	**C-2** Match request to test sample	**C-3** Prepare patient (mentally, physically), prepare animals	**C-4** Obtain and lable sample/specimen	**C-5** Handle, transport, store sample, including legal requirements
D: Process Materials	**D-1** Organize Compounds	**D-2** Prepare buffers, reagents	**D-3** Set up and work reactions	**D-4**	**D-5**
E: Control Inventory	**E-1** Monitor and Record inventory, keep census of animals	**E-2** Order supplies, reagents, animals	**E-3** Date, Label, store supplies and or reagents, identify animals	**E-4** verify incoming delivery accuracy	**E-5** Check expiration dates and lot numbers.

F: Maintain Equipment and Facility	**F-1** Check calibration and perform system diagnostics	**F-2** Validate or confirm processes, equipment, facilities, kits, vendor products	**F-3** Perform or schedule preventive maintenance	**F-4** Clean work area according to SOPs	**F-5** Sample environment
G: Observe and Document Safe Practices	**G-1** Maintain and follow chemical hygiene plan	**G-2** Follow universal precautions for biological pathogens	**G-3** Use protective equipment	**G-4** Observe rules of safety with radioactive materials	**G-5** Observe rules of electrical safety
H: Comply with current Accreditation And Government Regulations	**H-1** Follow regulations: FDA(GMPs and GLPs)	**H-2** Follow regulations (OSHA)	**H-3** Follow regulations (for example USDA)	**H-4** Follow regulations NIH[1] (National Institute of Health)	**H-5** Follow regulations CDC[2] (Centers for Disease Control and Prevention)

I: Maintain Quality Assurance	**I-1** Inspect, release incoming inventory	**I-2** Check, verify integrity of the product, procedure, specimen	**I-3** Use test standards, controls	**I-4** Maintain QA logs,	**I-5** Follow policies and procedures
J: Evaluate, Document and Report Results	**J-1** Collect data	**J-2** Perform Calculations	**J-3** Perform basic statistical analysis	**J-4** Evaluate validity of results	**J-5** Identify abnormal results
K: Communicate and Document Information (written, Oral, Electronic)	**K-1** Interact with vendors, colleagues, and clients	**K-2** Coordinate tasks with coworkers	**K-3** Write or update protocols, procedure manuals and reports for validation	**K-4** Write memos and letters	**K-5** Make oral presentation

L: Perform Initial Research	**L-1** Assist with design of research protocol	**L-2** Research Literature	**L-3** Maintain laboratory notebook		
M: Care For Research Animals/Plants	**M-1** Monitor health and maintain health records	**M-2** Feed and water animals/plants	**M-3** Receive and transport animals/plants	**M-4** Monitor housing conditions	**M-5** Restrain and handle animals
N: Maintain Professional Competency	**N-1** Participate in training and cross-training.	**N-2** Maintain awareness of accreditation and government regulations	**N-3** Participate in continuing education and professional organizations	**N-4** Pursue additional certification and degrees	**N-5** Read technical literature

Job Functions and Tasks of a Bioscience Technical Specialist

A-6 Perform tests /assays, chemical biological, clinical, environmental, robotic, mechanical	**A-7** Perform histotechniques where needed	**A-8** Return, archive, or dispose of samples				
B-6 Start up production	**B-7** Operate reactors, and recover products	**B-8** Obtain, Process, and product samples (applies to all manufacturing steps)	**B-9** Purify product	**B-10** Formulate, fill and inspect product	**B-11** Lable and package product	**B-12** Distribute final product

C-6 Asses acceptability / appropriateness of specimen						
E-6 Maintain separate in process, quarantine, and release areas	**E-7** Maintain and store manufactured products inventory					
F-6 Implement systems updates	**F-7** Maintain equipment logs	**F-8** Troubleshoot and repair equipment (work order)	**F-9** Lable equipment and facilities	**F-10** Ensure clean room integrity		

G-6 Attend required trainings	**G-7** Handle, contain and dispose of hazardous materials	**G-8** Maintain safety equipment	**G-9** Observe procedures for the safe use of instruments and cylinders			
H-6 Follow regulations: CLIA[3]	**H-7** Follow regulations: NRC[4]	**H-8** Follow state and local regulations:	**H-9** Follow Industry and professional regulations:			
I-6 Monitor production lines	**I-7** Document customer complaints	**I-8** Take and document corrective action according to SOP or as directed	**I-9** Participate in proficiency testing	**I-10** Ensure turnaround time		

J-6 Document and report test results	**J-7** Obtain written or verbal verification					
K-6 Process information using computers	**K-7** Notify appropriate persons about problem and observations	**K-8** Document communication of information				
M-6 Clean housing and sterilize cage	**M-7** Participate as a member of the research team	**M-8** Monitor and maintain animal safety				
N-6 Document training	**N-7** Promote community education	**N-8** Maintain professional demeanor				

It can be seen from the table 3.2 that good amount of details have been provided for clearly understanding typical tasks. With these, it is possible to go ahead with job description by identifying unit operations. (Tasks are broken down into unit operations for converting them into jobs which can be performed by an individual)

3.6 Tools and Equipment

While taking stock of resources for operational aspects it is appropriate to have a look at the tools and equipment used by Bioscience Technical Specialist.[6] It is useful to list the typical instruments and machinery for accomplishing the tasks, which is a concern of the management.

Table 3.3 Tools and Equipment used by Bioscience Technical Specialist

Tools and Equipment used by Bioscience Technical Specialist	
Anaerobic Hood	Incinerator
Assorted hand tools	Incubators
Assorted Clamps	Intercom
Assorted cleaning chemicals	Laminar-Flow hood
Autoclave/sterilizer	Laser particle counter
Automated urine analyzer	Laser
Automated integrity tester	Magnetic stir plates
Automated chemical analyzers	Mass spectrometer

Tools and Equipment used by Bioscience Technical Specialist	
Automated coagulation analyzers	Microscopes
Automated microbiology systems	Microtomes
Automatic diluting systems	Mixers/Shakers
Balance	Multi-meter
Bioreactors	Nitrogen storage tanks
Blood gas analyzers	NMRs
Cages and related equipment	Oil Baths
Calculators	Oscilloscope
Carboys	Osmometer
Cell counters (auto or manual)	Ovens and driers
Cell washers	Pagers
Centrifuges	pH meter
Colorimeter	Phosphor imager
Columns (reverse phase, ion exchange, affinity, HPLC, FPLC)	Photocopier
Computer hardware	Pumps

Tools and Equipment used by Bioscience Technical Specialist	
Computer software	Reference materials
Concentrators/ultra filtration units	Refractometer
Condensers	Refrigerators, freezers
Conductivity meters	Rotators
Cryostats	Rotovaps
Dark room and equipment (BK: photographic equipment)	Safety hoods
Densitometer	Safety equipment
Desiccators	Scales, balances
Dishwasher	Scintillation counters, coulter counters, gamma / beta counters
Electron microscope	Scoopers
Electrophoresis equipment	Shields
FAX	Specimen collection supplies
Filters	Spectrometer
Flame Photometer	Spectrophotometer
Fluorescent microscope	Stainer
Freeze driers	Sterilizers (Large)

Tools and Equipment used by Bioscience Technical Specialist	
Gamma counter	Surgical equipment
Gas chromatography mass spectrometer	Syringes and needles
Geiger counter	Telephone
Glassware	Thermocyclers/PCR reactions
Heating block	Thermometer
Hemocytometer	Timers
High pressure vacuum (pumps)	Tissue processors/homogenizers
Holding tanks	Tubes
Hoses / germicides	Ultracentrifuges
Hot plates	Ultra filtration unit
Pipettes / micropipettes	UV light
Plate reader	Voltmeter
Power supplies	Vortex
Pressure gauges	Water baths
Printers	Water Purification systems

As an example, the influence of cGMP-The Regulatory Environment for Biological Pharmaceutical Manufacturing, on operational details of bio manufacturing can be reviewed by referring to appendix III.

With the background which has been described up till now, the knowledge, skills and attributes for different divisions of manufacturing, described in the flow chart for the same can be described as information for understanding the HR parameters necessary for planning and development.

3.7 Typical Skills, Knowledge and Attributes for a Bioscience Technical Specialist

Table 3.4 Skills Knowledge and Attributes for Bioscience Technical Specialist[7]

General Work Skills	Industry Related Skills
Basic Math (Fractions, Percentages, Metric System)	Animal Care and Handling
Communication (Electronic, Oral, Written)	Aseptic Technique
Computers / Comfort with automation	Detail orientation
Critical Thinking	Following Complex Procedures
Decision Making	Identifying Irregular Results
Ethics (Business, Medical, Personal)	Instrumentation
Organization Skills	Inventory and supply maintenance
Personal Professional Development	Laboratory Procedure (Basic)
Prioritizing Tasks	Maintaining Records, Logs, Protocols

Problem Solving	Manual Dexterity
Resource Management	Performance consistency
Teamwork	Stress Management
Time Management	Troubleshooting Ability
TQM (total quality management)	Upkeep of Equipment / work area
	Writing logical instructions
Industry-Related knowledge	
Anatomy	Molecular Biology (Laboratory)
Animal Science	Organic Chemistry (Laboratory)
Basic Electronics (Laboratory)	Phlebotomy
Biochemistry (Laboratory)	Physiology (Laboratory)
Biology (Laboratory)	Quality Control and Quality
Botany	Assurance Practices
Career Awareness Within the Industry	Recognizing need for supervisory assistance
Chemistry (Laboratory)	Regulatory Standards
Clinical Laboratory Sciences	Safety Systems
Engineering	Scientific Systems
Immunology (Laboratory)	Terminology (Medical, Bioscience)

Industry-Related knowledge	
Math (Graphing, Ratios, Calculus)	Toxicology
Microbiology (Laboratory)	

The above description is typical and from this the qualification and experience of candidates who will be doing the work can be worked out. As the work has to be performed in an organization, the personality attributes are also thought of and are described. This information is requirement of HR planning and development as well as organizational design. (This is a part of table 3.4)

Attributes

Accountability	Observant
Alertness	Patience
Common Sense	Positive Attitude
Compassion	Professional Attitude (Behaviour)
Confidentiality	Reliability
Conscientiousness	Responsibility
Courteousness	Safety Consciousness
Creativity	Scientific curiosity
Flexibility	Self Motivation
Handles Constructive Criticism	Sound Judgment

Handles Failure	Tactfulness
Hard Working	Takes initiative
Honesty	Thoroughness
Independent worker	Willingness to ask for help
Integrity	Willingness to work around hazardous chemicals
Interest in work	Willingness to work around Microbiologic Pathogens
Leadership	Willingness to work around Radioactive Materials
Meticulousness	Works well with many different people

With the above information as a typical basis and line of thinking, the issue of Organizational Design and Process can be discussed.

3.8 Organizational Design and Process[8]

The organizational design and process provides important inputs for the HRM functions, more particularly to human resource planning and development functions. Therefore, review of important points from this topic is necessary for clarifying the basic issues in the process of HR Planning and Development. They have been discussed here to that extent only.

A key issue in accomplishing the goals identified in the planning process is structuring the work of the organization.

- Organizations are groups of people, with ideas and resources, working toward common goals.

- The purpose of the organizing function is to make the best use of the organization's resources to achieve organizational goals.
- Organizational structure is the formal decision-making framework by which job tasks are divided, grouped, and coordinated.
- Formalization is an important aspect of structure**.** It is the extent to which the units of the organization are explicitly defined and its policies, procedures, and goals are clearly stated.
- Organizational structure is conceived and built by top management. The formal organization can be seen and represented in a chart form.
- An organization chart displays the organizational structure and shows job titles, lines of authority, and relationships between departments.

3.8.1 Organization Design

Designing an organization is choosing an organizational structure that will make it easier for the company to achieve its goals most effectively. Organization design is the creation of an organization's structure. Traditionally it has been of the following types, viz. **Functional, Divisional,** and/or **Matrix.**

3.8.1.1 Functional Organization: Functions or divisions arrange traditional organizations. In a **Functional Organization**, authority is determined by the relationships between group functions and activities. Functional structures group similar or related occupational specialties or processes together under the familiar headings of finance, manufacturing, marketing, accounts receivable, and research. Economy is achieved

through specialization. However, the organization risks losing sight of its overall interests as different departments pursue their own goals.

3.8.1.2 Divisional Organization: here corporate divisions operate as relatively autonomous businesses under the larger corporate umbrella. In a conglomerate organization, divisions may be unrelated. Divisional structures are made up of self-contained strategic business units that each produces a single product. A central headquarters, focusing on results, coordinates and controls the activities, and provides support services between divisions. Functional departments accomplish division goals. A weakness however, is the tendency to duplicate activities among divisions.

3.8.1.3 Matrix Organization: in Matrix, teams are formed and team members report to two or more managers. **Matrix Structures** utilize functional and divisional chains of command simultaneously in the same part of the organization, commonly for one-of-a-kind projects. It is used to develop a new product, to ensure the continuing success of a product to which several departments directly contribute, and to solve a difficult problem. By superimposing a project structure upon the functional structure, a matrix organization is formed that allows the organization to take advantage of new opportunities. This structure assigns specialists from different functional departments to work on one or more projects being led by project managers. The matrix concept facilitates working on concurrent projects by creating a dual chain of command, the project (program, systems, or product) manager and the functional manager. Project managers have authority over activities geared toward achieving organizational goals while functional managers have authority over promotion decisions and performance reviews.

Matrix organizations are particularly appealing to firms that want to speed up the decision-making process. However, the matrix organization may not allow long-term working relationships to develop. Furthermore,

using multiple managers for one employee may result in confusion as to manager evaluation and accountability. Thus, the matrix system may elevate the conflict between product and functional interests.

3.8.2 Organizing Function

The organizing function deals with all those activities that result in the formal assignment of tasks and authority and a coordination of effort. The supervisor staffs the work unit, trains employees, secures resources, and empowers the work group into a productive team. The steps in the organizing process include

1. Review plans
2. List all tasks to be accomplished
3. Divide tasks into groups-one person can accomplish- a job
4. Group related jobs together in a logical and efficient manner
5. Assign work to individuals
6. Delegate authority to establish relationships between jobs and groups of jobs.

The nature and scope of the work needed to accomplish the organization's objectives is necessary to determine work classification and work unit design. **Division of Labor**, or work specialization, is the degree to which tasks in an organization are divided into separate jobs. Work process requirements and employee skill level determine the degree of specialization. It is obvious that placing capable people in each job ties directly with productivity improvement. In order to maximize productivity, supervisors match employee skill level with task requirements.

Supervisors perform workflow analysis to examine how work creates or adds value to the ongoing processes in an organization. **Workflow Analysis** looks at how work moves from the customer or the

demand source through the organization to the point at which the work leaves the organization as a product or service to meet customer demand. Thus, workflow analysis can be used to tighten the connection between employees' work and customers' needs.

3.8.3 Departmentalization

After reviewing the plans, usually the first step in the organizing process is departmentalization. Once jobs have been classified through work specialization, they are grouped so that common tasks can be coordinated. **Departmentalization** is the basis on which work or individuals are grouped into manageable units. There are five traditional methods for grouping work activities.

3.8.3.1 Departmentalization by Function organizes by the functions to be performed. The functions reflect the nature of the business. The advantage of this type of grouping is obtaining efficiencies from consolidating similar specialties and people with common skills, knowledge and orientations together in common units.

3.8.3.2 Departmentalization by Product assembles all functions needed to make and market a particular product are placed under one executive.

3.8.3.3 Departmentalization by Geographical Regions groups jobs on the basis of territory or geography.

3.8.3.4 Departmentalization by Process groups jobs on the basis of product or customer flow. Each process requires particular skills and offers a basis for homogeneous categorizing of work activities.

3.8.3.5 Departmentalization by Customer groups jobs on the basis of a common set of needs or problems of specific customers. A current departmentalization trend is to structure work according to customer, using **Cross-Functional Teams**. This group is chosen from different functions to

work together across various departments to interdependently create new products or services. For example, a cross-functional team consisting of managers from accounting, finance, and marketing is created to prepare a technology plan.

3.8.4 Generic Components of Organizational Structure

A According to (organizational configuration model[9]) Mintzberg, an organization can consists of a maximum of six basic parts (Fig. 3.3)

The simple description of these six parts is as follows

1. Strategic Apex : Top Management
2. Middle Line : Middle Management
3. Operating Core (Operations, Operational Processes)
4. Techno structure (Analysts who design systems, Processes, etc)
5. Support Staff (Support outside of operating workflow)
6. Ideology (Halo of beliefs and traditions, Norms, Values, Culture)

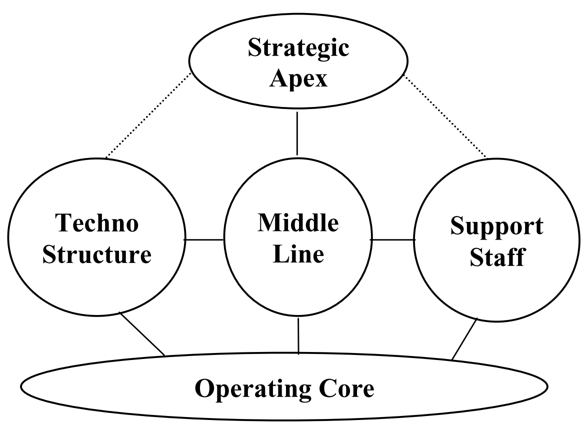


Fig. 3.3 Generic Components of Organizational Structure

The reader may note that the "**Techno Structure**" was first referred to in chapter I and the significance of this discussion of organization design process becomes clear in the context of the present study.

For biotechnology business, the choice of organization design is vested with the top management and at this juncture this review is sufficient because whatever may be the choice of the top management, this step is essential for planning of the workforce or Human Resource and subsequently for development of HR. After this, theoretical framework of Human Resource Management as it pertains to present study is presented.

3.9 Human Resource Management

There are many ways in which HRM is defined and during the course of evolution of strategic management, the HRM is also being described in terms of strategic approaches. One such definition is given below:

"*HRM is a strategic approach to managing employment relations which emphasizes that leveraging people's capability is critical to achieving sustainable competitive advantage, this being achieved through a distinctive set of integrated employment policies, programs and practices.*[10] *"*

The above definition has **'Emphasis on People'** as one of the most important competitive advantages a company can create.[11] People are the only element with the inherent power to generate value. All the other variables offer nothing but inert potential. By their nature, they add nothing, and they cannot add anything until some human being leverages that potential by putting it into play.[12]

When technology based organizations are under consideration, the above statements are truer because the:

- Potential of the technology for value addition can only be harnessed by people with necessary education and skill.
- This creates a demand that top management attract, cultivate, and keep the best workforce they can possibly find.
- This makes the role of human resources as important if not more as any other executive leadership function.

In recent times human resource management (HRM) has assumed new prominence because of continuing concerns about global competition, the internationalization of technology and the productivity of labor. It is argued that these market imperatives require managers to change the way in which they manage the employment relationship in order to allow for the most effective utilization of human resources (HR). Managers and academics argue that the traditional approaches to managing workers are inappropriate and 'can no longer deliver the goods' The seminal book New perspectives on Human Resource Management, edited by John Storey (1989), generated the 'first wave' of debate on the nature and ideological significance of the 'progressive' HRM model. This debate on the alleged shift from personnel management to the HRM model has been particularly fierce among academics in many countries (Storey, 1995). By the late 1990s, a 'second wave' of debate emerged with four distinct themes:

1. The significance of the economic and social context in shaping and reshaping the HRM arena; (Maybey et.al, 1998).
2. The links between HRM and organizational performance
3. The new organizational forms and relationships and
4. The importance of 'knowledge' management and learning in the workplace

With this brief review of the HRM process, it is easier to understand the functions covered under this process of management of human resources.

3.10 Human Resource Management Functions

HRM encompasses a body of knowledge and a set of policies and practices that shape the nature of work and regulate the employment relationship. Drawing on Squires' (2001) work, these practices suggest some basic questions: 1.What do HRM professionals do? and 2.What affects what they do?

We will draw on the work of Millward et al. (1992, 2000) and Ulrich (1997) to identify eight key HRM functions, policies and practices designed in response to organizational goals and contingencies, and managed to achieve those goals. Each of the eight functions viz. 1.Planning, 2.Staffing, 3.Developing, 4.Motivating, 5.Maitaining, 6.Managing relationships, 7.Managing change and 8. Evaluating contains alternatives from which managers can choose.

3.10.1 Planning: preparing forecasts of future HR needs in the light of an organization's environment, mission and objectives, strategies, and internal strengths and weaknesses, including its structure, culture, technology and leadership.

3.10.2 Staffing: obtaining people with the appropriate skills, abilities, knowledge and experience to fill jobs in the work organization. Key practices are human resource planning, job analysis, recruitment and selection.

3.10.3 Developing: analyzing learning requirements to ensure that employees possess the knowledge and skills to perform satisfactorily in their jobs or to advance in the organization. Performance appraisal can identify employees' key skills and 'competencies'

3.10.4 Motivating: the design and administration of reward systems. HR practices include job evaluation, performance appraisal, pay and benefits.

3.10.5 Maintaining: The administration and monitoring of workplace safety, health and welfare policies, educational benefits to retain a competent workforce and comply with statutory standards and regulations.

3.10.6 Managing Relationships: encompasses a range of employees' involvement/participation schemes in non-union or union workplaces. In a union environment, this includes negotiating contracts and administrating the collective agreement.

3.10.7 Managing Change: this involves helping others to envision the future, communicating this vision, setting clear expectations for performance and developing the capability to reorganize people and reallocate other resources.

3.10.8 Evaluating: designing the procedures and processes that measure, evaluate and communicate the value-added component of HR practices and the entire HR system to the organization.

3.10.9 Why only HRP and D?

Though eight functions of HRM have been described above, for the purpose of the present study researcher has chosen only Human Resource Planning and Development. The eight functions mentioned above can be analyzed for finding out overlapping areas and priorities within them.

In the beginning of this chapter the discussion of operational and organizational design aspects of biotechnology business was done. Typical tasks of a bioscience specialist were also described. The different type of organization structures have been discussed after noting the six basic and generic components of organization. It should be remembered here that

most important functions for organizational designing are Human Resource Planning and Development. It can be easily understood that unless the planning and development functions are taken care of in a scientific manner, the other functions of HRM which are secondary and complimentary functions will not be able to organize the work. The parameters like job descriptions and job specifications, demand and supply position of required manpower, the kind of organizational structure chosen by top management etc. are of primary importance and have priority over other remaining functions. The planning and development are technology specific functions and others are not so technology specific. The component of technology is understood and taken care of during implementation of these two primary functions. From the point of view of management, if the HR planning and Development functions are taken care of, the other functions can be considered subsequently in the course of tackling the issues of organizational management. This also limits the scope of study, and though this is a limitation from HRM point of view, it is acceptable to choose planning and development as primary functions for study. It will also be noticed that as staffing follows planning and precedes development, it has automatically been included in enquiry. Except evaluation (as described above), all the other five functions have been directly or indirectly touched upon during the course of study and for drawing inferences, conclusions etc.

A brief review of related literature on human resource planning and development for generating proper perspective and linkages to biotechnology operations and organizations is presented in the following lines.

3.11 Human Resource Planning

Human Resource planning owed its importance to business strategy and planning in many organizations. It is worth paying attention to the

process of planning at this level. **A plan represents one of the outcomes of a process that seeks to find a solution to a defined problem.** There have been many attempts to rationalize this process to provide a set of easy-to-follow linear steps so that efficient decisions can be made to formulate a plan from a choice of alternatives prior to implementation.

Plans represent the precise and unified articulation of an organizations strategy, produced as a result of a rational consideration of the various issues that affect an organization's future performance before making a choice of the action required. Senior managers during this process conduct an appraisal of both internal and external situations using a range of techniques to assess the organization's Strengths and Weaknesses and the Opportunities and Threats affecting it – the so-called SWOT analysis.

Formally, the emphasis will be on data that can be quantified, which is not surprising since the planning process itself is an organization's attempt to preempt and deal with identified problems and uncertainty, and numbers are certain precise and simple to comprehend. This image of certainty and control is one that gives comfort to many senior managers, although, as argued by Mintzberg et al. (1998), the field of strategic management is filled with division and competing versions of how strategy actually works.

If business strategy and plans find their expression in measurable financial, marketing and production targets with an implicit or explicit demand for people, the human resource plan represents a response by the personnel function to ensure that the necessary supply of people is forthcoming to allow the targets to be met. The rationalized approach to human resource planning and its key stages are shown in Figure 3.4

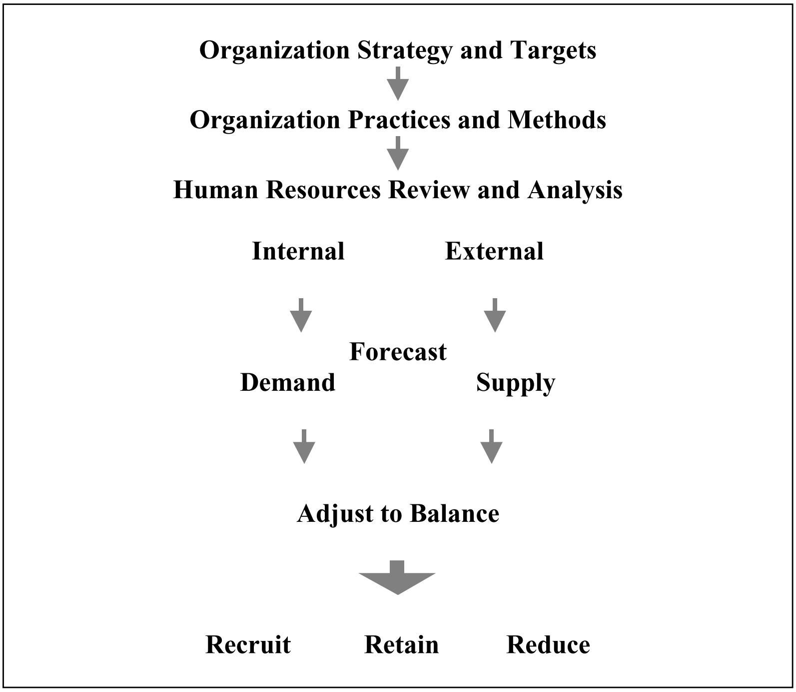


Figure 3.4 Rationalized Approach to Human Resource Planning

In 1974, the Department of Employment (US) defined human resource planning as:

It is a Strategy for the acquisition, utilization, improvement and preservation of an organization's human resources.

This definition was broad and general enough to cover most aspects of personnel management work. Four stages of the planning process were outlined:

1. An evaluation or appreciation of the existing manpower resources.
2. An estimation of the proportion of currently employed manpower resources that were likely to be within the firm by the forecast date.

3. An assessment or forecast of labor requirements if the organization's overall objectives were to be achieved by the forecast date.
4. Measures to ensure that the necessary resources were available as and when required, that is, the human resource plan.

Stages 1 and 2 were linked in the **'Supply Aspect of Human Resource'** with stage 1, being part of normal personnel practice'. Stage 3 represents the **'Demand Aspect of Human Resource.'** There were two main reasons for companies to use human resource planning: first, to develop their business objectives and manning levels; and second, to reduce the unknown factor.

In the diagnostic approach to human resource planning, quantitative planning techniques are used in combination with qualitative techniques to identify and understand the causes of human resource problems. This information can then be used to generate solutions equal to the complexity of the problems. Such an approach has the potential to affect organizational structure, job design and work practices. Organizations can also work out short-term tactics to deal with external human resource issues such as skill shortages and a decline in the number of young people in the labor market. In both the diagnostic approach and the rationalized approach, human resource plans are established with reference to a predetermined strategy. However, HRP seeks to make the links between strategy, structure and people more explicit.

Throughout the 1990s and into the 2000s, there is ongoing debate over what kind of approach to HRM should be adopted in order to provide superior performance at work. There have been a number of efforts to explore the link between HRM practices and the bottom line. Although it is suggested that such efforts may lack consistency in methodology and provide different results, studies in general show that there is some benefit

in adopting a 'high road' HRM strategy of **high training, high involvement, high rewards and quality commitment** (Cooke, 2000). In contrast 'low road' HRM is characterized by low pay, low job security and work intensification.

In addition to the general view of adopting a 'high road' HRM strategy, further research suggests the importance of introducing HR practices together in a 'bundle' so that they enhance and support each other (Cooke, 2000). Planning to introduce appraisal on its own will, for example, be far less effective without a consideration of training, reward, careers and the attitudes and styles of managers. It is also important to coordinate the implementation (Hoque, 1999), which highlights the importance of a more sophisticated view of HRP.

A 'high road' HRM strategy requires a belief by senior management that people represent the key source of competitive advantage because an organization's route to success is based on distinctive product and / or service quality as well as price. Furthermore, the continuing development of those people will be a vital feature of strategy in both its formation and its implementation. In this version HRP builds on and develops the rationalized and diagnostic approaches to planning. It may certainly involve the use of human resource modeling, simulations and statistical techniques, but these will be set within an overall approach to planning that will underpin the bundle of interdependent policies and activities, with the emphasis on human resource management (Legge, 1995).

Although there is increasing evidence for a link between 'high road' HRM and business performance, such evidence may not always convince senior managers in their decision-making. Liff (2000) suggests that HRP implies a link to the resource-based view of firms in which market opportunities are considered against a firm's internal resources when setting strategy. Thus, a consideration of the **distinctive expertise and**

skills of people is held to be a first order element of making the strategy. There is, however, also significant evidence that many firms the world over do not view people in this way, preferring to see HRM issues as a third order issue (Coleman & Keep, 2001). Furthermore, when faced with difficulties, many organizations swiftly move towards the 'hard' version of HRM in which HR activities are designed to respond to strategy, people being viewed as a resource whose cost must be controlled. The emphasis is on human *resource management (*Legge, 1995). Taking the road from strategy, HRP is in this version concerned more with the right number of people at the right place at the right time that can be utilized in the most cost-effective manner.

This is a pattern that has been repeated across many organizations. HRP has been used to provide a framework to accommodate 'multifarious practice' of 'pragmatic and opportunistic' organizations (Storey, 1995a). Thus, at the same time as HRP can respond to the direction provided by changes in organizational structure and strategy to cut costs and staff numbers, a trend referred to as 'downsizing', it can also provide the means by which to achieve desirable HR outcomes such as commitment and high performance. Indeed, those involved in the formation and delivery of HR plans may sometimes feel the conflicts and pressures referred to earlier, requiring an interesting game of words to maintain the appearance of sense.

3.12 Integrating HR Planning with Business Activities

The discussion in the above paragraphs assumes that HRM is an independent function to be handled by a separate HR team. There are totally different views presented by some thinker for organizations which are more technology based. One such view by James W. Walker is presented below.

James W. Walker makes a cogent case for the integration of HR planning with other business activities. In chapter 22 (The Ultimate Human Resources Planning: Integrating the Human Resources Function with the business) of Handbook of Human Resource Management[13] he argues that because HR planning deals with one of the firm's critical resource needs, it must in the framework of organization's general strategy. If an organization practiced completely integrated human resource planning, HR might "blend into the fabric of management and cease to exist as a staff function."

In the conclusion of the chapter Walker mentions that the integration of human resources function with the business will be a result of more aggressive human resource planning in companies. This begins with formulating and implementing strategies to address people-related business issues. It then requires enabling managers to manage people effectively, through processes that focus on increasing organizational effectiveness. It also requires redefining the human resources staff function, its organization, roles, and capabilities, and culminates with defining and applying business measures of human resource effectiveness, focusing on the business impact.

Human resource planning provides the facilitating process necessary to achieve integration of human resource management sub functions with each other and with the business. To the extent that it is applied, our understanding of the mission, roles, processes, activities, and measures of the human function will change radically. The function may, even ideally, blend into the fabric of management and cease to exist as a separate staff function. In this way, the management of people will become integral to business performance.

The review presented above gives us information about the past present and future of HRP and can be useful background for putting the

practices being followed by the selected biotech businesses in a proper perspective. For putting the development aspect in proper perspective the review is continued in the context of development.

3.13 Human Resource Development

Human resource development means the procedures and processes that purposely seek to provide learning activities to enhance the skills, knowledge and capabilities of people, teams and the organizations. This is done so that there is a change in action to achieve the desired outcomes.

Human resource development (HRD), as an organizational investment in the learning of its people, acts as a powerful signal of its intentions. There is an indication that a longer-term view is being taken, particularly with respect to the outcomes of HRD, by replacing the words ‘training costs’ with ‘investment,’. There is a significant contrast with the view of training as a short-term cost, which has persistently acted as a powerful break on many training strategies.

- HRD implies that learning will be a strategic consideration.
- HRD acts as a triggering mechanism for the progression of other HRM policies that are aimed at recruiting, retaining and reward employees, who are recognized as the qualitative difference between organizations. The investment in employee learning is a way of creating a primary internal market, and policies aimed at progressively upgrading skills reduce an organization’s dependency on external sources of skill.
- If an organization is seeking to adopt ‘high road’ HRM strategy (chapter 6, Cooke, 2000), engendering the conditions whereby loyalty and commitment towards an organization’s aim can be encouraged, HRD carries the prospect of unleashing the potential that lies within all people, allowing employees to contribute to

and indeed transform strategy.

In recent years, ideas and practices relating to HRD have moved beyond a narrow conception of training and development. Many organizations now attempt to take a new holistic view that embraces the idea of learning at individual and organizational levels as a crucial source of competitive advantage. HRD has attempted to move out of training departments into every aspect of organizational life as many organizations claim attraction to the idea of a learning organization, with increasing moves towards finding ways to integrate work and learning. Technology, global markets, customer expectations and competition have all contributed to the view that organizations need to achieve 'high performance working', leading to the generation of high value added products and services for customers, and trust and commitment from enthusiastic employees (International Labor Organization, 2000, p.1). Key features of such an approach are the attention paid to learning throughout the organization and the fact that learning is the only strategy to cope with change. There is a growing emphasis on viewing an organization as a total learning system and finding its 'core competencies' which reveal its 'collective learning' (Prahlad and Hamel, 1990, p.82). In addition, continuing advances in information technology have fostered an e-learning movement, and accelerating change has stimulated a growing interest in organizational learning and knowledge management, the development of an organization's intellectual capital (Edvinsson & Malone' 1997) and the potential for learning between organizations.

These are indeed powerful notions that have made learning at work a 'hot topic' (Grey, 1998), feeding the message that learning is an obvious 'good thing'. One important consequence is a growing interest in the profession of HRD and its theoretical development. HRD practitioners, for example, form a significant section of the Chartered Institute of Personnel

and Development (CIPD) in the UK where they are able to present themselves as the experts in the development of knowledge, skills and learning, and as proactive in their approach to change (Mankun, 2001). Accompanying this growth, there has been more focus on the theoretical basis of HRD (Woodall, 2001), new journals and conferences being devoted to HRD as a separate discipline rather than a sub discipline of HRM.

"However, not all organizations have responded to the message of the virtues of HRD. There continues to be a lack of investment in workforce learning, causing significant concern in government. Furthermore, some of the assumptions that underpin an organization's investment in people are questioned, especially if they are framed in terms of the mutual interest of employees and employers in the benefit of learning at work" (Rainbird, 2000).

After putting the process of HRD in perspective by way of presenting the review of its development now the linkage between strategy and human resource development is discussed.

3.14 Strategy and Human Resource Development

In most formulations of HRM, training, employee development and any other learning activities that form an organization's HRD provisions represent significant if not pivotal components. Aston and Felstead (1995, P 235), for example, regard the investment by an organization in the skills of employees as a 'litmus test' for a change in the way in which they are managed. Of the 'bundle' of HR practices required for a 'high road' HRM strategy (Cooke, 2000,p.5), HRD has a pivotal role in the integration of practices to create an internal labor market with links to organizational structure and strategy. A key image, as mentioned above, is that of high-performance working (International Labor Organization, 2000), in which high-level skills and high discretion in the performance of work allow a

decentralization of decision-making to those closest to customers. Associated with such a view is the importance attached to learning, especially within self-managed teams; team members are able to define their own learning needs (Stern and Sommerlad, 1999).

It has, however, long been recognized that there are some key elements of organizational context that will limit and constrain the design of HRM policies and their implementation, what Guest (1989, p. 50) referred to as the 'cement' that binds the system to ensure a successful outcome to HRM policies. Included in the 'cement' are both the support of leaders and senior managers and a culture that reinforces HRM.

Two important implications arise from this view.

1) Employees are recruited for a skilled working role that will require learning and change, rather than for a job that might soon become obsolete. Employees are expected to retrain, and indeed many employees undertake courses of self-study in order to continue their learning and remain 'employable'. Employees are therefore carefully selected as much for-their ability to learn as for their current repertoire of skills. Once recruited, employees become worth investing in, although the form of this investment may be subtler than simply possessing a large training budget. That is, learning becomes embedded into workplace practice as an ongoing process.

2) Line managers are fully involved in the development of their subordinates, to such an extent that the differentiation between learning and working becomes virtually impossible to discern (and include in a budget). There is an emphasis on informal learning and an appreciation of its value, which line managers regard as part of their job and a responsibility on which they will be assessed. It is the acceptance of this responsibility, more than any other within HRM, by line managers, that carries the potential to produce the outcomes of loyalty, flexibility, quality

and commitment. Not least of these outcomes is that more formal HRD activities, such as training courses, are likely to prove their value, but transfer of learning into the workplace can also alter the nature of work itself and the relationships between managers and employees. Thus, line managers would carry out the process linking performance, appraisal and development effectively as part of their normal work, resulting in the assessment of the need for job improvement and career development.

Foundation for organizational designs for biotech companies were discussed in the beginning of this chapter, and to help study the HRM aspects and more particularly the HRP and D aspects of biotech it is necessary to discuss the knowledge and skills required in biotechnology business. That has been covered in the next chapter.

3.15 Conclusion

The biotechnology industry was born through the commercialization of academic research. New companies are often “spun-off” from university research laboratories. They are built around an idea and talented individuals. A founding scientist in a particular company may also be director of research in a hospital and a professor at a university. The research process successful at laboratories in the universities is termed as academic research. When the same results are successfully converted into commercial products and services it is labeled as industrial activity of the spun of biotech company.

As a company develops, different skills sets are required at different stages of growth. For early-stage R&D companies, skills are more closely linked to traditional research knowledge and capabilities in the specific field. In the normal process of development a potential product is chosen and developed toward commercialization. Increasingly rigorous analytical and investigative studies are required under defined levels of discipline as the product moves down the regulatory path toward licensing. In addition

to research competence, skills and knowledge are required in pre-clinical trials in design of an optimal regulatory path, in quality assurance (QA) and quality control (QC) and in process engineering as production methods are scaled up. Once the product is fully developed and has received any necessary approvals, marketing, manufacturing and production management become important and HRP and D have to become prominent.

Organizational structure is a subject related to HRM and HRP and D activities are closely linked with organization of any business. As has been reviewed, the biotech business at present is pharmaceutical product oriented and therefore the resources required for organizing the same have been described in greater details. After the basic drug discovery research and approval through regulatory channels, it is manufacturing and engineering required for the same become central. These and other necessary divisions of business have been described to the extent necessary for understanding the HRP and D issues in the biotechnology businesses at present times.

Organizational design and process provides necessary backdrop for HRP and D activity and detailed review of theoretical aspects of the same is presented for the same purpose. The very important and integral part of any organization, which is human resource and its management aspect, is dealt with in details after that, where the information about theoretical parameters of human resource necessary so as to understand the dynamics of planning and development have been reviewed in detail.

It can be easily understood that along with the latest technology required for competitive advantage, availability of employees with the necessary skills sets is a key factor in the continued growth of a successful biotechnology sector. That is the subject matter of the next chapter IV Knowledge, Skill sets and job positions in biotechnology businesses.

ENDNOTES

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[1] http://www.ncbiotech.org/pdffiles/goldenleafrpt.pdf
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[2] National Institute of Health. U.S. Department of health and human Services. http://www.nih.gov/

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[4] Clinical Laboratory Improvement Amendments (CLIA) http://www.fda.gov/cdrh/CLIA/index.html

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Chapter IV

Knowledge, Skill Sets and Job Positions in Biotechnology Business

4.0 Introduction

Chapter II has satisfied the objective number one i.e. to trace the origin and growth of biotech businesses and to gain understanding of biotech sector in terms of technology basics, main applications, and extent of global spread with revenue and employment generation.

Chapter III satisfied the objectives number 2 and 3. The objective number two i. e. to understand the organizational development of typical biotechnology industry in terms of the different skill sets and tasks required for biotech business process and objective three-to review theoretical aspects of HRM as required for developing proper perspective of HRP and D for biotech businesses.

The objective number four of the study is to gain understanding of knowledge and skills about typical job positions available in biotech organization, with job descriptions and job specifications. Explore experiences from other countries. An attempt has been made here so as to satisfy this objective in this chapter.

As has been understood from the description in the chapter II that biotechnology is a symbiotic combination of many technologies like molecular biology, genetic engineering, chemical technology, information technology etc. it is essential to understand the knowledge base required before developing the understanding about the skill sets required in the biotechnology business. After this has been understood, development of understanding of typical job positions with job descriptions and job specification becomes easier to comprehend and hence have been discussed in this chapter in the same order.

4.1 Knowledge and Skills in Biotechnology Businesses[1]

The knowledge and skills which employees in bio manufacturing or pharmaceutical manufacturing need to possess are described here. Some of this knowledge base is commonly taught in colleges and universities. Commercial training providers that serve the industry teach other parts of the knowledge base. Those topics that are not covered by both of these sources are difficult to access outside the industry. One of the challenges in preparing the workforce will be to bring materials, methods and trainers from all these sources together to develop training programmes at all the different educational levels as appropriate. Following is typical complete description of all the fields and topics that are the foundation for work in the manufacturing side of biotechnology operations. This also serves as necessary parameter of Human Resource Management as has been discussed in chapter III.

4.1.1 General Knowledge Base

4.1.1.1 Biology: General Biology, Microbiology, Virology, Immunology, Cell biology, Biochemistry, Protein chemistry, Molecular genetics, Environmental sciences, Occupational health, Toxicology

4.1.1.2 Chemistry: General chemistry, Inorganic chemistry, Organic chemistry Analytical chemistry, Physical chemistry, Pharmaceutical chemistry

4.1.1.3 Mathematics: Basic lab math, Calculus, Statistics, Mathematical modeling, Trending analysis

4.1.1.4 Computer science: Word processing, Spreadsheets, Database use/management, Programming, Networking/network management

4.1.1.5 Engineering Curricula: Mechanical, Electrical, Chemical, Biochemical, Biomedical, Material science

4.1.1.6 Business courses/workshops: Business/ technical writing and communication, Business economics, Organizational psychology, Teamwork principles /practices, Supervisory skills, Project management

4.1.2 Industrial Knowledge and Skills Sets

The general knowledge base described in the section above prepares a candidate for working in the industry with the additional industry specific knowledge base and skill sets. The biotechnology industry specific industrial knowledge base and skill sets are described in the following lines. Explanation for all them is subsequently given while job descriptions and specifications are presented.

4.1.2.1 Regulatory Compliance: This is a set of regulatory norms required to be followed and complied with for biotech operations. GMP principles and procedures, GLP principles and procedures, GCP principles and procedures, QA principles and procedures, SOP writing, Validation methodology, Validation study design, Industrial safety practices, Laboratory safety practices, Safety audits, OSHA regulations (**O**ccupational **S**afety & **H**ealth **A**dministration) Environmental regulations-waste disposal, Environmental health and safety

4.1.2.2 Maintenance and Engineering: Facility design, Facility commissioning and qualification, Electrical systems, Mechanical systems, HVAC (Heating, Ventilating & Air Conditioning), Pipefitting, Power distribution, Instrumentation, Utility systems, Process equipment maintenance.

4.1.2.3 Instrumentation and Process Control: Measurement of process variables, Instrumentation calibration, Process control system operation, Process control system tuning, Process control system design/programming, Metrology

4.1.2.4 General Process Operations: P & IDs (Piping & Instrumentation Diagrams), Equipment Commissioning, Common Pumps, Piping, Valves, Tanks, Solid Handling Equipment, CIP & SIP Systems (Cleaning-In-Place & Sterilization-In-Place Systems), Clean-out-of –Place and Sterilize-out-of-Place Operations, Heat Exchangers, Evaporators, Condensers, Chemical Materials Handling, Transport, Storage, Biological Materials Handling, Transport, Storage, Simple Mixing and Dosing Operations, General Equipment Inspection, Monitoring.

4.1.2.5 Unit Operations: Batch Chemical Reaction Operations, Continuous Chemical Reaction Operations, Distillation / Stripping, Growth Media Prep for Mammalian Cells, Growth Media Prep for Microbial Cells, Bioreactor Operation for Mammalian Cell Cultures, Bioreactor Operation for Microbial Cell Cultures, Bioreactor Operation for Other Types of Cultures, Cell Disruption, Centrifugation, Depth Filtration, Membran Filtration (micro/ultra/nano/RO), Diafiltration, Chromatography-Affinity,Chromatography-Ion-Exchange, Chromatography-Hydrophobic-Interaction,Chromatography-Size Exclusion, Liquid-Liquid Extraction, Precipitation, Crystallization, Lyophilization (freeze-drying), Granulation, Pasteurization/Flow-through Sterilization, Immobilized Enzyme Technology

4.1.2.6 Pharmaceutical Manufacturing Technology: Solid Dose Forms Preparation, Aerosol Formulation, Injectable Formulation, Filling, Sterile Filling, Other Aseptic Operations, Work in Clean Rooms, Working in Laminar Flow Hoods, Isolation Technology

4.1.2.7 Process Development / Optimization: Process Design, Equipment Selection/Sizing/Designing, Scale-up Principles, Raw Materials Selection/Specifications, Material and Energy Balance, Mass Transfer Modeling /Calculations, CAD

4.1.2.8BasicLaboratory Work: Glassware Selection/Use/Cleaning, Making Solutions/Dilutions, Measuring pH/Titration, Basic Equipment Calibration, Calorimetric Assays-Manual, Calorimetric Assays-Automated, Microscopy-Basic, Microscopy-Phase Contrast, Microbiological Culture Methods, Mammalian Cell Culture Methods, Sampling Techniques, Sample Labeling/Handling Storage

4.1.2.9 Analytical Instrumentation: UV/Visible Spectrophotometer, Fluorescence Spectroscopy, Infrared Spectroscopy, NMR Spectroscopy, Mass Spectrometry, Atomic Absorption Spectroscopy, Gas Chromatography, HPLC, Refractrometry, Polarimetry

4.1.2.10 Other Analytical / Laboratory Methods: Dry Weight Determinations, Dissolution Assays, Flame Tests, Environmental Monitoring Methods, Toxicology Assays, Laboratory Animal Care, RIA/ELISA Assays (**R**adio**i**mmuno**a**ssay) (**E**nzyme-**l**inked **i**mmunoas**sa**y), Other Immunoassay Methods, Enzyme Assays, PCR(Polymerase Chain Reaction), Electrophoresis(a method that separates macromolecules-either nucleic acids or proteins-on the basis of size, electric charge, and other physical properties.), Capillary Electrophoresis, Chromatography, Standard, FPLC (Pharmacia **F**ast **P**rotein **L**iquid **C**hromatography system is used for methods development and the purification of large quantities of various biomolecules i.e., protein and DNA).

After Knowledge and Skill sets description the typical job positions available in Biotechnology enterprise can be understood. They have been described below.

4.2 Job Positions in a Biotechnology Enterprise

The activities are grouped suitably. This grouping is labeled as departmentalization, in the context of organization design. Typical to biotechnology operations eight such groups or departments have been discussed in this section.

4.2.1 Research & Development: (8 Positions)

1 Glass Washer

2 Laboratory Assistant

3 Research Associate

4 Research Assistant

5 Postdoctoral Fellow

6 Media Prep Technician

7 Greenhouse Assistant

8 Plant Breeder

4.2.2 Quality Control: (6 Positions)

1 Quality Control Analyst

2 Quality Control Engineer

3 Environmental Health and Safety Specialist

4 Quality Assurance Auditor

5 Validation Engineer

6 Validation Technician

4.2.3 Clinical Research: (10 Positions)

1 Clinical Research Administrator

2 Clinical Coordinator

3 Clinical Programmer

4 Biostatistician

5 Clinical Data Specialist

6 Drug Experience Coordinator

7 Clinical Research Associate

8 Animal Handler

9 Animal Technician

10 Technical Writer

4.2.4 Manufacturing & Production: (10 Positions)

1 Product Development Engineer

2 Production Planner Scheduler

3 Manufacturing Technician

4 Packaging Operator

5 Manufacturing Research Associate

6 Instrument Calibration Technician

7 Biochemical Development Engineer

8 Process Development Associate

9 Assay Analyst

10 Manufacturing Engineer

4.2.5 Regulatory Affairs: (3 Positions)

1 Regulatory Affairs Specialist

2 Documentation Coordinator

3 Documentation Specialist

4.2.6 Information Systems: (2 positions)

1 Library Assistant

2 Scientific Programmer Analyst

4.2.7 Marketing and Sales (5 Positions)

1. Market Research Analyst

2. Systems Analyst

3 Sales Representative

4 Customer Service Representative

5 Technical Services Representative

4.2.8 Administration: (5 Positions)

1 Technical Recruiter

2 Human Resources Representative

3 Buyer

4 Patent Administrator

5 Patent Agent

The organizational set up typical to biotechnology reviewed above is related to core functions in biotechnology as special business requirements. It should be noted by the reader that the qualifications mentioned in the job descriptions presented in the next section are of US/Indian standard and appropriate variation for any other location has to be kept in mind where similar qualification are available. These are useful for evaluation and planning human resources requirements on the basis of specific project an organization would want to undertake in any of the applications viz. agricultural, industrial, environmental, pharmaceutical etc. these Sectorial divisions or descriptions and priorities thereof would be function of several external factors like market requirements, regulatory norms, availability of funds, technology transfer and most important is availability of suitably trained manpower at entry level as well as manpower with suitable experience for startup. The other administrative management support including HR and personnel is of course required and is an integral part of any business organization.

4.3 The Job Descriptions and Specifications[2]

The job descriptions and specifications given here are typical which are found in the industry. The following is a list of typical, entry-level and other biotechnology positions, followed by job descriptions. Many of the entry-level biotechnology jobs described herein are the first of several tiers within the same general areas of responsibility listed as follows.

Research and Development, Quality Control, Clinical research, Manufacturing and Production, Regulatory Affairs, Information Systems, Marketing & Sales, Administration,

Job descriptions and Job specifications are given department wise with Job title and Job description (technical skills, and necessary soft skills are implicit, and have not been mentioned here) and Entry level requirements.

4.3.1 Research and Development: (8 positions)

There are in all eight typical positions that are required as mentioned in 4.2.1. The typical job description with entry level qualifications and experience, are described below

4.3.1.1 Glass Washer: A glass washer is responsible for washing and drying glassware and distributing it to appropriate locations within the laboratories. S/he maintains the glass-washing facility, keeping it clean and swept, and picks up dirty glassware. S/he may sterilize glassware and other items using an autoclave. A glass washer performs routine maintenance of glass-washing equipment and performs other related duties as required.

Qualifications: Diploma or equivalent

Experience: 0 to 2 years laboratory experience.

4.3.1.2. Laboratory Assistant: Laboratory assistants are responsible for performing a wide variety of research laboratory tasks and experiments, making detailed observations, analyzing data, and

interpreting results. S/he may maintain laboratory equipment and inventory levels for laboratory supplies. S/he may also write reports. Making written summaries and protocols regarding experiments is important. A laboratory assistant also performs limited troubleshooting and calibration of instruments.

Qualifications: Degree or equivalent

Experience: 0 to 2 years laboratory experience.

4.3.1.3. Research Associate: A research associate is responsible for research and development in collaboration with others on projects. S/he makes detailed observations, analyses data, and interprets results. Research associates prepare technical reports, summaries, protocols, and quantitative analyses. An incumbent maintains familiarity with current scientific literature and contributes to the process of a project within his or her scientific discipline, as well as investigating, creating, and developing new methods and technologies for project advancement. He or she may also be responsible for identifying patentable inventions and acting as principal investigator in conducting his or her own experiments. A research associate may also be asked to participate in scientific conferences and contribute to scientific journals.

Qualifications: Doctoral Degree or equivalent with experimental research in the field of activity

Experience: 0 to 2 years research experience.

4.3.1.4. Research Assistant: Similar to that of a research associate, mentioned in 4.3.1.3

Qualifications: Masters degree or equivalent with experimental work in the field of activity

Experience: 0 to 1 years research experience.

4.3.1.5. Postdoctoral Fellow: Work with the staff for a maximum of two to three years to gain necessary experience before moving onto a more senior scientist position

Qualifications: Ph. D. in the field of activity

Experience: Little or no job experience

4.3.1.6 Media Prep Technician: A media prep technician is responsible for media preparation in the research and development area. He or she performs experiments as required and outlined, and develops and maintains record keeping for procedures and experiments performed.

Qualifications: Degree or equivalent

Experience: 0 to 2 years and/ or completion of on the job training.

4.3.1.7. Greenhouse Assistant: A greenhouse assistant performs a variety of greenhouse research tasks and experiments. S/he may be required to make detailed observations, detecting horticultural or pest problems, and instituting corrective action. Greenhouse assistants determine optimal cultural requirements and perform tasks related to disease and pest prevention; they often are required to collect, record, and analyze data, as well as interpret results. In addition a greenhouse assistant may be called upon to perform troubleshooting and equipment maintenance.

Qualifications: Diploma, Degree or equivalent

Experience: 0 to 2 years greenhouse/plant experience and or completion of on the job training.

4.3.1.8. Plant Breeder: A plant breeder is responsible for the design, development, execution, and implementation of plant breeding research projects in collaboration with a larger research team. S/he may be responsible for project planning and personnel management within the project. Plant breeders may use exotic germ plasm and work with various

mating systems and integrate them with biotechnology as needed to enhance selection methods and accelerate product development.

Qualifications: B.Sc. Degree or equivalent

Experience: 0 to 2 years related experience in plant breeding / agronomy, and /or completion of training in plant breeding/plant science.

4.3.2 Quality Control. (6 positions)

4.3.2.1. Quality Control Analysts: A quality control analyst is responsible for conducting routine and non-routine analysis of raw materials. He or she compiles data for documentation of test procedures and reports abnormalities. A quality control analyst also reviews data obtained for compliance with specifications and reports abnormalities. He or she revises and updates standard operating procedures and may perform special projects on analytical problem solving.

Qualifications: B.Sc. Degree or equivalent

Experience: 0 to 2 years experience in quality control systems

4.3.2.2. Quality Control Engineer: A quality control engineer is responsible for developing, applying, revising, and maintaining quality standards for processing materials into partially finished or finished products. S/he designs and implements methods and procedure for inspecting, testing, and evaluating the precision and accuracy of products and prepares documentation for inspection of testing procedures. Depending on the job level, a quality control engineer is responsible for ensuring conformance to in-house specifications and good manufacturing practices and may conduct training programs. He or she may also be responsible for and supervise the development efforts of a quality control engineering group.

Qualifications: B.Sc. Degree or equivalent

Experience: 0 to 2 years related experience in quality control systems

4.3.2.3. Environment Health and Safety Specialist: An environment health and safety specialist is responsible for developing, implementing, and monitoring industrial safety programs within the company. S/he inspects plant areas to ensure compliance with Occupational Safety and Health Administration regulations. S/he evaluates new equipment and raw materials for safety, and monitors employees exposure to chemicals and other toxic substances. A safety specialist, depending on the job level, may also conduct training programs in hazardous waste collection, disposal, and radiation safety regulations.

Qualifications: B.Sc. Degree or equivalent

Experience: 0 to 2 years related experience

4.3.2.4. Quality Assurance Auditor: A Quality Assurance Auditor is responsible for performing audits of production and quality control. S/he ensures compliance to in-house specifications, standards, and good manufacturing practices.

Qualifications: B.Sc. Degree or equivalent

Experience: 0 to 2 years related experience in biological or pharmaceutical manufacturing

4.3.2.5. Validation Engineer: A Validation Engineer is responsible for the calibration and validation of equipment systems and for assisting in the selection, specification, and negotiation of competitive pricing of equipment. S/he maintains all of the documentation pertaining to qualification and validation and serves as an information resource for validation technicians, contractors and vendors.

Qualifications: B.Sc. Degree or equivalent

Experience: 0 to 2 years related experience

4.3.2.6. Validation Technician: An entry level validation technician would be responsible for developing, preparing the installation of, and revising test validation procedures/protocols to ensure that a product is manufactured in accordance with appropriate regulatory agency validation requirements, internal company standards, and current industry practices. A validation technician compiles and analyzes validation data, prepares reports, and makes recommendations for changes and /or improvements. S/he may also investigate and troubleshoot problems and determine solutions. S/he maintains appropriate validation documentation and files.

Qualifications: Diploma or equivalent

Experience:0 to 2 years laboratory experience.

4.3.3 Clinical research (10 positions)

4.3.3.1. Clinical Research Administrator: A clinical research administrator is responsible for clinical data entry and validation to ensure legibility, completeness, and consistency of data. S/he assists users with requests clinical documents and is responsible for working with physicians and /or their staff to clarify any questionable information. He or she may be responsible for auditing internal patient files and studies and for assisting with the development and evaluation of clinical record documents. At the entry level s/he typically develops internal record keeping system(s), including maintaining and auditing data and providing status and activity reports as required.

Qualifications: Diploma or equivalent

Experience: 0 to 2 years related experience.

4.3.3.2. Clinical Coordinator: A Clinical coordinator must be familiar with the scientific/investigative process. Expertise may be limited to a specific functional area. A clinical coordinator must have good

communication skills both written and oral. S/he must also have project team experience and a familiarity with standard computer applications. Responsibilities include coordinating the clinical development plan as outlined by the company or clinical department, defining objectives, strategy and studies. The clinical coordinator must provide support for planning, including detailed effort estimates, scheduling, and critical path analysis. He or she must monitor clinical activities to identify issues, variances, and conflicts, and analyze and recommend solutions. The clinical coordinator is responsible for project staffing requirements and tracking drug supply to outside vendors, as well as providing ongoing, objective updates on progress and problems with projects, tracking and following up on action items.

Qualifications: B.Sc. or equivalent in health science, Information technology, business

Experience: 3 to 5years related experience in healthcare industry.

4.3.3.3. Clinical Programmer: A beginner clinical programmer is responsible for coordinating and monitoring flow of clinical data into the computer database. S/he analyses and evaluates clinical data, recognizes inconsistencies, and initiates the resolution of data problems. He or she implements data management plans designed to meet project and protocol deadlines, and consults in the design and development of clinical trials, protocols, and case report forms. A clinical programmer also acts as liaison between clinical management and subcommittees and project teams on an as-needed basis.

Qualifications: B.Sc. or M. Sc. equivalent in health science, Information technology, business administration.

Experience: 1 to 2 years related experience in pharmaceutical programming in the clinical research area.

4.3.3.4. Biostatistician: A Biostatistician works with others to define and perform analyses of databases for publications, presentations to investigator meetings, and for meetings of professional societies

Qualifications: M. Sc. equivalent in Biostatistics

Experience: 1 to 2 years related experience

4.3.3.5. Clinical Data Specialist: A clinical data specialist is responsible for collaborating with various departments on the design, documentation, testing and, implementation of clinical data studies. He or she develops systems for organizing data to analyze, identify, and report trends. A clinical data specialist also analyzes the interrelationships between data and defines logical aspects of data sets.

Qualifications: B. Sc. equivalent

Experience: 1 to 2 years related experience

4.3.3.6. Drug Experience Coordinator: The major responsibility of a drug experience coordinator is to handle the drug experience activities for marketed products. The candidate will also provide drug information on the products. He or she will oversee day-to-day processing of adverse event information for marketed products and will coordinate the receipt, classification, investigation, and processing of adverse experience reports.

Qualifications: B. Pharm. equivalent /clinical training

Experience: 1 to 2 years related experience

4.3.3.7. Clinical Research Associate: A clinical research associate is responsible for the design, planning, implementation, and overall direction of clinical research projects. He or she evaluates and analyzes clinical data and coordinates activities of associates to ensure compliance with protocol and overall clinical objectives. He or she may also travel to field sites to supervise and coordinate clinical studies.

Qualifications: B. Sc. equivalent /Nurse Degree training, Knowledge of Drug Authority regulatory requirements is also preferred.

Experience: 1 to 2 years related experience in medical research, nursing or the pharmaceutical industry

4.3.3.8. Animal Handler: An animal handler is responsible for the daily care of research animals for experimental purposes. He or she cleans animal cages and racks, maintains records to comply with regulatory requirements and standard operating procedures, and performs preventive maintenance on facility equipment. The incumbent may also perform animal observation, grooming, and minor clinical tasks.

Qualifications: Diploma or equivalent

Experience: 1 to 2 years related experience

4.3.3.9. Animal Technician: Animal technicians are responsible for the daily care of research animals for experimental purposes. They also coordinate with vendors and supervisors on operational, administrative, and technical responsibilities. They perform some surgery and postoperative care as directed and are responsible for overseeing procurement of animals and supplies, preventive maintenance of facility equipment, cleaning of animal cages and racks, daily rounds, and observation to check animal health status. They develop standard operating procedures and maintain records to comply with regulatory requirements.

Qualifications: Diploma or equivalent

Experience: 1 to 2 years related experience

4.3.3.10. Technical Writer: An entry-level technical writer is responsible for writing and editing standard operating procedures, clinical study protocols, laboratory procedure manuals, and other related documents. He or she edits and/or rewrites various sources of information into a uniform style and language for regulatory compliance, and assists in

developing documentation for instructional, descriptive, reference, and/or informational purposes. An entry-level position requires a Bachelor of Science degree or equivalent and a minimum of 0 to 2 years of experience in writing technical documentation.

Qualifications: B.Sc. or equivalent with proficiency in technical writing .

Experience: 1 to 2 years related experience in writing technical

4.3.4 Manufacturing and Production (10 positions)

4.3.4.1. Product Development Engineer: A product development engineer, at the entry level, is responsible for the design, development, modifications to, and enhancements of existing products and processes. The position is involved in new product scale-up, process optimization, technology transfer, and process validation. He or she ensures that processes and design implementations are consistent with good labor and manufacturing practices. A product development engineer may also be responsible for contact with outside vendors and for the administration of contracts to accomplish goals. A product development engineer works on problems of moderate scope, where analysis of a situation or data requires a review of identifiable factors.

Qualifications: B.E. or equivalent with management qualification

Experience: 1 to 2 years related experience

4.3.4.2. Production Planner Scheduler: A production planner scheduler is responsible for planning, scheduling, and coordinating the final approval of products through the production cycle. He or she coordinates production plans to ensure that materials are provided according to schedules to maintain production and provides input to management. When necessary, a production planner scheduler works with the Customer Service, Marketing, Production, Quality Control, and Sales

departments to review back order status, prioritize production orders, and deal with other potential schedule interruptions or rescheduling. An entry-level production planner scheduler requires a bachelor's degree or equivalent and a minimum of 0 to 2 years' related experience.

Qualifications: B. E. or equivalent with management qualification

Experience: 1 to 2 years related experience

4.3.4.3. Manufacturing Technician: Manufacturing technicians are responsible for the manufacture and packaging of potential and existing products. They operate and maintain small production equipment; weigh, measure, and check raw materials, and ensure that manufactured batches contain the proper ingredients and quantities. They maintain records and clean production areas to comply with regulatory requirements, good manufacturing practices, and standard operating procedures. A manufacturing technician may also assist with in process testing to make sure that batches meet product specifications.

Qualifications: Diploma in Engineering or equivalent with management qualification.

Experience: 1 to 2 years related experience in a manufacturing environment.

4.3.4.4. Packaging Operator: A packaging operator uses manual and/or automated packaging systems to label, inspect, and package final container products. He or she also enters data and imprints computer-generated labels, maintains records, and maintains the manufacturing/ production area to comply with regulatory requirements, good manufacturing practices, and standard operating procedures. A packaging operator may also perform initial checks of completed documents for completeness and accuracy.

Qualifications: Diploma in Engineering or equivalent.

Experience: 1 to 2 years related experience in a manufacturing environment.

4.3.4.5. Manufacturing Research Associate: A manufacturing research associate is responsible for the implementation of production procedures to optimize manufacturing processes and regulatory requirements, and has responsibilities in packaging and distribution processes. He or she may also help maintain production equipment.

Qualifications: Diploma in Engineering or equivalent

Experience: 1 to 2 years related experience in a manufacturing environment.

4.3.4.6. Instrument / Calibration Technician: An entry-level instrument/calibration technician is responsible for performing maintenance, testing, troubleshooting, calibration, and repair on a variety of circuits, components, analytical equipment, and instrumentation. He or she also calibrates instrumentation, performs validation studies, and specifies and requests purchase of components. He or she analyzes results, may develop test specifications and electrical schematics, and maintains logs and required documentation. An instrument/calibration technician also maintains spare parts inventories and may prepare technical reports with recommendations for solutions to technical problems.

Qualifications: Diploma in electronics technology/Engineering or equivalent

Experience: 1 to 2 years related experience in a manufacturing environment.

4.3.4.7. Biochemical Development Engineer: A biochemical development engineer is responsible for the design and scale-up of processes, instruments, and equipment from the laboratory through the pilot plant and manufacturing process. He or she assists the manufacturing

operations in problem solving with regards to equipment and systems and participates in the design and start-up of new manufacturing facilities and equipment. He or she develops and recommends new process formulas and technologies to achieve cost effectiveness and product quality. A biochemical development engineer also establishes operating equipment specifications and improves manufacturing techniques. A biochemical development engineer is involved in new product scale-up, process improvement, technology transfer, and process-validation activities. He or she works with various departments to ensure that processes and designs are compatible for new product technology transfer and to establish future process and equipment automation technology.

Qualifications: B.E. biological, chemical or pharmaceutical engineering or equivalent

Experience: 1 to 2 years related experience preferably in the areas of pharmaceutical processes or research product development.

4.3.4.8. Process Development Associate: A process development associate is responsible for the implementation of production procedures to optimize manufacturing processes and regulatory requirements. He or she may also assist in process development, in creating scalable processes with improved product yield and reduced manufacturing systems costs. A process development associate, at the entry level, may also be involved in packaging and distribution processes and in the maintenance of production equipment. He or she may research and implement new methods and technologies to enhance operations.

Qualifications: B.E. biological, chemical or pharmaceutical engineering or equivalent

Experience: 1 to 2 years related experience preferably in the areas of pharmaceutical processes or research process development.

4.3.4.9. Assay Analyst: An assay analyst is responsible for doing cell cultures and performing assays and tests on tissue and cell cultures following standard protocols. He or she prepares glassware, reagents and media for cell culture use. He or she also performs, prepares and maintains tissues and cell cultures and maintains records required by good manufacturing procedures. An assay analyst also participates in the modification of assay procedures for routine implementation.

Qualifications: Diploma in cell culture or equivalent

Experience: 1 to 2 years related experience

4.3.4.10. Manufacturing Engineer: A manufacturing engineer is responsible for developing, implementing, and maintaining methods, operation sequences, and processes in manufacturing. He or she works with the engineering department to coordinate the release of new products. He or she estimates manufacturing costs, determines time standards, and makes recommendations for process requirements of new or existing product lines. As required, a manufacturing engineer also maintains records and reporting systems for the coordination of manufacturing operations.

Qualifications: B.E. biological, chemical or pharmaceutical engineering or equivalent

Experience: 1 to 2 years related experience preferably in the areas of pharmaceutical processes or research product development or a manufacturing environment.

4.3.5 Regulatory Affairs (3 positions)

4.3.5.1. Regulatory Affairs Specialists: A regulatory affairs specialist, at the entry level, coordinates and prepares document packages for submission to regulatory agencies, internal audits, and inspections. He or she compiles all material required for submissions, license renewals,

and annual registrations. An incumbent monitors and improves tracking and control systems and keeps abreast of regulatory procedures and changes. He or she may work with regulatory agencies and recommend strategies for earliest possible approvals of clinical trial applications.

Qualifications: B.Sc. Or equivalent.

Experience: 0 to 2 years' related experience.

4.3.5.2. Documentation Coordinator: A documentation coordinator provides clerical and administrative support related to a company's documentation system requirements. He or she audits all documentation manuals to ensure that they are accurate and up-to-date and available to appropriate personnel. A documentation coordinator also files and retrieves all master documents.

Qualification: Diploma or equivalent with proficiency in English and computer usage

Experience: 0 to 2 years' related experience.

4.3.5.3. Documentation Specialist: An entry-level documentation specialist is responsible for coordinating all activities related to providing required documentation and implementing related documentation systems. He or she coordinates the review and revision of procedures, specifications, and forms. He or she also assists in compiling regulatory filing documents and in maintaining computerized files to support all documentation systems.

Qualification: B. Sc. in related field with proficiency in English and computer usage

Experience: 0 to 2 years' experience in documentation, quality assurance, technical writing or the equivalent.

4.3.6 Information Systems (2 positions)

4.3.6.1. Library Assistant: A library assistant maintains serial control, and locates and orders journal articles and/or books that are unavailable at local libraries on relevant subjects. He or she performs special data-gathering projects as requested, and is responsible for on-line computer searching of scientific databases.

Qualification: B. Sc. in related field with proficiency in English and computer usage

Experience: 0 to 2 years' relevant library experience or the completion of an on-the-job training program.

4.3.6.2. Scientific Programmer Analyst: Scientific programmer analysts design, develop, evaluate, and modify computer programs for the solution of scientific or engineering problems and for the support of research and development efforts. He or she analyzes existing systems and formulates logic for new systems. A scientific program analyst also devises logical procedures, prepares flow charts, performs coding, tests, and debugs programs. He or she provides input for the documentation of new or existing programs, and determines system specifications, input/output processes, and working parameters for hardware/software compatibility. An analyst also contributes to decisions on policies, procedures, expansion strategies, and product evaluations

Qualification: B.Sc. in related field with proficiency in English and computer usage

Experience: 0 to 2 years' relevant experience

4.3.7 Marketing & Sales (5 positions)

4.3.7.1. Market Research Analyst: A market research analyst is responsible for researching and analyzing the company's markets, competition, and product mix. He or she performs literature research, analyzes and summarizes data, and makes presentations on new market

and technical areas. He or she also analyzes the competitive environment, as well as future marketing trends, and makes appropriate recommendations. He or she conducts market surveys, summarizes results, and assists in the preparation, presentation, and follow-up of research proposals.

Qualification: M.B.A. in related field with proficiency in English writing skills and computer usage

Experience: 0 to 2 years of experience in market research, competitive analysis, and product planning, as well as excellent writing skills.

4.3.7.2. Systems Analyst: A systems analyst is responsible for system level software and for maintenance of the operating system(s), various layered products, system tuning, and various levels of user assistance. The systems analyst is responsible for the operation of all system software, performing upgrades, and maintaining related system and user documentation. He or she assists in the implementation of system validation and documentation, in system capacity planning, and system configuration. In addition, the systems analyst trouble shoots system-related problems and interacts with vendors.

Qualification: B. E. computer science and data processing or equivalent

Experience: 0 to 2 years of experience.

4.3.7.3. Sales Representative: A sales representative is responsible for direct sales of company products or services. He or she calls on prospective customers, provides product information and/or demonstrations, and quotes appropriate customer prices. A sales representative is also responsible for new account development and growth of existing accounts within an established geographic territory. A sales

representative must meet assigned sales quotas and may handle key company accounts or act as an account manager for national or major accounts. Depending on the level of the position, an experienced incumbent may also assist in the training of other sales representatives.

Qualification: B.Sc. in related field, Diploma in sales and marketing with proficiency in English and computer usage

Experience: 0 to 2 years of related sales experience and some knowledge of the company's products.

4.3.7.4. Customer Service Representative: Customer service representatives are responsible for ensuring product delivery in accordance with customer requirements and manufacturing capabilities and for responding to customer product inquiries and satisfaction issues. He or she answers telephones, takes product orders, and inputs sales order data into consumer data systems. He or she also investigates problems related to the shipment of products, credits, and new orders. He or she may also be responsible for sale order administration and/or inside sales.

Qualification: B. Sc. in a technical or scientific field with proficiency in English and computer usage

Experience: 0 to 2 years' related experience in diagnosing and troubleshooting products in the pharmaceutical industry may also be required.

4.3.7.5. Technical Services Representative: A technical services representative provides technical direction and support to customers on the operation and maintenance of company products. He or she also serves as a contact for customers on technical and service-related problems. A technical services representative also demonstrates uses and advantages of products.

Qualification: B. Sc. in a technical or scientific field with proficiency in English and computer usage

Experience: 0 to 2 years of experience.

4.3.8 Administration (5 positions)

4.3.8.1 Technical Recruiter: A technical recruiter is responsible for recruiting, interviewing, and screening applicants for technical exempt and nonexempt positions. He or she coordinates pre employment physicals, travel, reporting dates, security clearances, and employment processing for new hires. He or she also conducts employee advertising and reviews employment agency placements. In addition, a technical recruiter maintains college recruiting, affirmative action, and career development programs.

Qualification: B. Sc. in a technical or scientific field. B.B.A.(HR)

Experience: 0 to 2 years' related experience

4.3.8.2. Human Resources Representative: A representative in human resources is responsible for a variety of activities in personnel administration, including employment, compensation and benefits, employee relations, equal employment opportunity, and training programs. He or she conducts job interviews, counsels employees, maintains records, and conducts research and analyzes data on assigned projects.

Qualification: B. Sc. in a technical or scientific field. M.B.A.(HR)

Experience: 0 to 2 years' related experience

4.3.8.3. Buyer: A buyer is responsible for obtaining materials, scientific equipment, and services. He or she checks requisitions, obtains price quotations, examines bids, and awards contracts. A buyer develops new supply sources where vendors and suppliers are inadequate. He or she coordinates purchasing activities with other departments to maintain inventory at planned levels. As required, a buyer also monitors the cost,

schedule, and scope of assigned subcontracts to ensure the quality and value of the contract..

Qualification: B. Sc. in a technical or scientific field with proficiency in English and computer usage

Experience: 0 to 2 years' related experience in purchasing, preferably in a scientific area.

4.3.8.4. Patent Administrator: A patent administrator is responsible for preparing and coordinating all procedural documentation for patent filings and applications. He or she tracks in-house research studies and recommends the need for and timing of patent filings. A patent administrator also assists attorneys with the drafting and editing of patent applications and collects and evaluates supporting data. This position requires the maintenance of a tracking system to comply with trademark regulations. He or she may also be called upon to assist with determining the necessity and approach to contracts to ensure protection of the company's proprietary technology. A patent administrator is also typically responsible for tracking and paying legal fees.

Qualification: B. Sc. in a technical or scientific field, Training in patent laws and procedures, Proficiency in English and computer usage.

Experience: 0 to 2 years' related experience

4.3.8.5. Patent Agent: A patent agent is responsible for preparing, filing, and processing patent applications for the company. He or she negotiates and drafts patent licenses and other agreements. A patent agent also conducts state-of-the-art searches and may assist with appeal and interference proceedings. A patent agent also performs other duties as required.

Qualification: B. Sc. in a technical or scientific field, Training in patent laws and procedures, necessary regulatory registrations for

practicing before patent and trademark office, with proficiency in English and computer usage.

Experience: 0 to 2 years' related experience

It should be remembered here that these are descriptions for typical positions that are available with a biotechnology enterprise. They have been listed with Job title and Job description (implicit technical skills, necessary soft skills).Entry level requirements, and are for reference at HR management function. They can be used for designing organization and for HRP and D purposes.

In addition to the above, the report "Assessing Workforce Needs in the Biotechnology Industry[3]" by Rochester Institute of Technology, October 2000, was also useful in listing biotech skill sets which we need to understand as an important part of the study. That has been made use of while framing the questions regarding technical skill sets for biotech businesses.

The skill sets used for planning and development of human resources has been extensively used in the questionnaire which is used for surveying some selected companies. The description of the skill sets mentioned in the questionnaire has been covered in job specifications and descriptions. The specimen of the questionnaire is given in appendix I. and hence to avoid repetition, that information has not been mentioned here.

4.4 Biotech HR- Experiences from Other Countries

Globalization has changed the environment into competitive one. The field of business intelligence[4] has become important, for remaining competitive. Review of few important experiences of countries leading globally in the field of biotechnology can provide guidelines for human resource issues such as assigning responsibilities, training required, skills required, compensation, skills availability etc. A very brief review of

important reports from Canada, UK has been presented so as to increase understanding about the HR issues presented in this chapter

In a report entitled "Profile of the biotechnologies sector[5]" by Canadian organization mentions that "The industry currently employees a highly skilled workforce, with about 50 % of employment in research and development. However, the industry faces a critical shortage of skills associated with management and the commercialization of products under development."

"The skills most needed are those of managers with a science background and with expertise in business development, domestic and international regulatory requirements, technology transfer, strategic alliance development, production scale-up, and investor relations. Shortages also exist for quality control/quality assurance managers. Clinical trial managers and managers with expertise in intellectual property issues are required. **Managers with these skills are in short supply worldwide, and competition for qualified people is intense**."

The above statement can serve as a guideline for HR issues for other countries in the developing world as Canada happens to be the number two players in the Global biotech business while US is on first place. This is also supported by another survey report entitled "Identification of Management Skill Needs in the East of England Region Biotechnology Sector[6]"

Canadian biotechnology Human Resource Study (2004) entitled "converging science and Leadership-The key to the future[7]" is a very comprehensive report and is listed on their web site and one who is interested in the Human Resource aspect of the biotechnology business should make an attempt to download and read it for complete picture.

Management Talent- The Canadian biotechnology industry needs experienced managers that can guide company growth and move products

through the commercialization process to the market place. Managers of smaller firms need a mix of skills. They have to manage technology, find funding and develop alliances and deals that are required to achieve commercial success. In addition, they need all the skills required to run what is initially a small business that will likely grow rapidly.

Often the first manager of a firm is the founding scientist, who may not have the requisite business skills required to grow the business. While many have gone on to acquire the managerial skills needed for success, others need to make way for professional managers who can take firms forward. Canada has a relatively small pool of managers with this kind of unique expertise and experience. All too often, companies have had to import individuals with required skills and expertise mix from the larger pool in the US. This shortage of qualified people is impacting the growth of Canadian biotechnology.

Governance- The management problem spills over into firm governance. Finding seasoned board members who understand the trials and tribulations of biotechnology tends to be difficult because qualified board members typically need to have managerial experience. The problem can be partially, but not completely, overcome by calling on executives from larger established firms.

Attracting Top Talent- When companies recruit from abroad they encounter an expensive and uncertain recruitment process, high salary levels, immigration requirements, taxation issues and the fundamental problem of finding qualified people.

Employee Training and Development- In keeping with the notion that small firms want “job-ready” candidates, educators still need to blend scientific and technical training with basic business skills and related areas such as intellectual property and regulatory affairs.”

BHRC i.e. Biotech Human Resource Council in Canada is one of the important organization working especially on HR aspects and interested people should visit the website[8] for more information.

4.5 Conclusion

The description of typical organization of a biotech company along with job descriptions and job specifications is a basic foundation of the process of HRP and the organizational design and process provided in chapter III gives sufficient background for OD, training and development activities. Brief description of experiences from Canada and UK throws light on the human resource aspect of biotechnology business in globally leading countries on number two and number three ranks, which can provide HR guidelines for emerging biotech business in India and other countries.

ENDNOTES

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1 http://accessexcellence.org/AB/CC/

2 Biotech Job descriptions "Biotechnology: The choice for your future. A Resource Guide." 2004, Biotechnology Industry Organization. 6 Margaret Wheatley, Leadership and New science, 1994, p.144.

3 Center for Biotechnology Education and Training . Available at http://www.cbet.org/survey.doc

4 http://en.wikipedia.org/wiki/Business_plan

5 This publication is available electronically on the World Wide Web at the following address: http://acst-ccst.gc.ca/skills

6 Cranfield biotechnology centre Cambstec business link ERBI (Eastern Region Biotechnology Initiative) May 2000. http://www.erbi.co.uk

7 http://www.bhrc.ca/career/reports/downloadable/sectorStudy/index.cfm

8 http://www.bhrc.ca/career/reports/downloadable/index.cfm

Chapter V
Case Studies of Selected Biotechnology Companies

5.0 Introduction

The global overview in terms of historical growth, extent of spread and socio economic effects of biotech business was taken in chapter II. There it was seen that the United States of America is the leader and next in line are Canada and UK in Europe. India is in the Asia Pacific region where the biotech business is emerging and the contribution of Asia Pacific region to biotech revenue and employment at global level suggested that the biotech business in this region is in infant stage. In the beginning of the overview, in chapter II, scientific basics of biotechnology, definition of biotechnology and biotechnology business, special features of biotechnology, main applications of biotechnology, sectorial categorization or classification etc. was also discussed. Against this backdrop, the Indian biotech scenario, and case studies of few biotechnology companies are presented in detail in this chapter.

In the context of the present study the Indian Policy front for biotechnology, with apex institutions formed by government and their funding pattern is discussed. These government initiatives are discussed with a focus on HR parameters and after that the performance parameters of industries in India are discussed using the case study approach. This information for the period 2000- 2003 is discussed with relevant numerical data, analysis using percentile graphs, comparison of year wise employment number, turnover and composition of employees as per educational qualifications is also discussed. This provides a good background in terms of Indian scenario of biotechnology business at macro level. So as to go from macro level understanding to micro level understanding, case studies of four industries in this sector representing Bio-Pharma, Bio-Pharma + Industrial, Agricultural biotech are presented with relevant information and analysis for

the purpose of elucidating inferences about Human Resource Management issues. As acceptable in the inductive method the inferences which have drawn using these case studies become applicable to biotechnology businesses, more particularly in India.

5.1 Indian Biotech Business[1]

In the global biotech market, Indian share in 2003 was just about 2% however; the future seems very bright for the country. Biotechnology is a fast emerging sector in India. The consumption of biotech products in India was $ 1789 million during 1999, which is expected to grow to the tune of $4270 million by the end of year 2010.

5.1.1 Indian Initiatives for Biotechnology Business[2] -

Industry and academic institution's collaboration activity and foreign collaborations by Indian companies have received a major boost after 2000. These alliances involve contract research and manufacturing, co-marketing, technology transfer and joint Research & Development (R&D) agreements.

India is emerging as a partner of choice for several American and European companies because they are facing resource constraints. One of the ways for them for increasing productivity is to develop collaboration with companies with resources at a lower cost. Indian technical manpower is high quality and is available at relatively low cost. Several Indian companies have managed to cross IPR hurdles to work with international partners through confidentiality and non-disclosure agreements. The effective implementation of the WTO mandated product patent regime on the anvil will facilitate change in perception. In the wake of the new IPR regime, partnering is equally an imperative for Indian companies because they are pursuing a resource-intensive, product-driven model for sustainable growth. Indian biotech companies had initially copied the information technology sector's service based model to earn early revenues. India's major biopharmaceutical companies are now accelerating efforts to get

bioequivalent versions of patented, well-characterized recombinant proteins onto the market before 2005. The small biotech companies are focusing on innovative research, and are picking niches where there is little competition. Bioinformatics companies are other players who are benefiting from an intellectual property driven model.

According to Ernst and Young (market reports 2002- 2005), the market for generic biotech products will increase over the next few years, as many products will be coming off patent. India is emerging as major player in the development of a global market for bio-generics. India has positioned to take advantage of moves by Governments in the U.S. and Europe to create a regulatory framework for approving generic versions of successful protein drugs. Several new sources of capital and government policy changes will also benefit the Indian industry. These include allowing insurance companies to invest in biotech venture funds and the Indian government's decision to raise the cap for foreign investment. This will make it easier for foreign venture capitalists to invest in Indian biotech companies. Biotech has been relatively new ground for the Indian venture capital community, though there have been some initiatives like the APIDC[3] fund launched last year. **A**ndhra **P**radesh **I**ndustrial **D**evelopment **C**orporation Limited was established on 16th December 1960, by the Government of Andhra Pradesh for planned development of medium and large-scale industries in the state. Today, it has an authorized capital of Rs. 110 Crores and paid up capital of Rs. 96.23 Crores. APIDC offers a wide range of financial and consulting services. Services include but are not limited to Project promotion - Generation and Implementation of New Project Ideas, Guidance and Comprehensive Escort Service to the Entrepreneurs, Participation in Equity Capital, Providing Term Loans, Providing Bill Discounting Facility, Providing Guarantees, Merchant Banking, Venture Capital Fund for IT, BT Industry. This is a very good example of state government initiative and therefore has been quoted. There

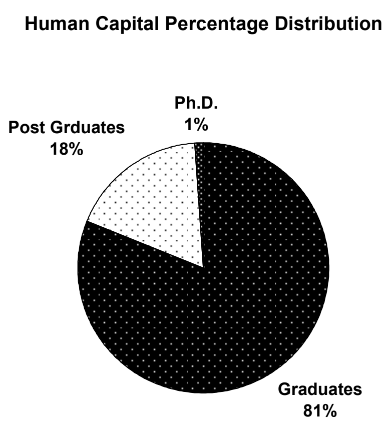
is also an announcement by the Department of Biotechnology and the Technology Development Board to launch funds.

Biotechnology is knowledge and skill based industry and India's rich human capital is believed to be the strongest asset for this. India is having a large English speaking skill base,

- **3 Million Graduates,**
- **700,000 Postgraduates and**
- **1500 PhDs qualified in Biosciences and Engineering.**
- **10% of Researchers and 15% of Scientists in Pharma/Biotech R & D in USA are of Indian Origin.**

This human capital situation is represented graphically (fig. 5.1) for the purpose of analysis in this and further chapters.

Fig. 5.1 Human Capital Percentage Distribution- Educational



The above discussion indicates that Biotech industry in India at present is at a threshold of tremendous growth. As can be seen from the human capital situation pie chart, the number of candidates having Ph.D.'s

qualified in biosciences and related engineering for research and manufacturing has to significantly increase. Some of the important features presenting evolution of Indian biotech industries are highlighted below.

5.1.2 Milestones- the First Decade

- **1978** – Country's first biotech company BIOCON- for industrial enzymes
- **1981** – Center for Cellular & Molecular Biology (CCMB) - for DNA and rDNA based research.
- **1984** – Institute for Microbial Technology, (IMTECH) -for R&D in microbial bio-processing.
- **1986 -** Department of Biotechnology (DBT), set up by Government of India -for promoting biotechnology at academic and industry levels.
- **1987** - National Institute of Immunology (NII) for Immunology Research.
- **1989** – Bangalore Genei starts operations to produce restriction enzymes & other tools for DNA based R & D.

5.1.3 Milestones - the Second Decade

- **1991** – National Center for Biological Sciences (NCBS) - to pursue R & D molecular biology.
- **1994** – Syngene International, **Country's first CRC (Contract Research Company)** Promoted by Biocon to offer R & D services in drug discovery based on modern biology.
- **1997** – Center for Biochemical Technology (CBT) to focus on Bioinformatics and Genomics.
- **1997** – Shantha Biotech launches India's first recombinant product, Hep B vaccine.

- **1998 –** Monsanto Research established an R & D center at IISc for plant genomics.
- **1998** – DBT approves Mahyco-Monsanto to conduct Bt cotton trials.

5.1.4 Milestones- the third decade

- **2000** – Four states, **Andhra Pradesh, Karnataka, Maharashtra and Tamil Nadu announce Biotech Initiatives.**
- **2000** – Country's first bioinformatics company Strand Genomics formed by four IISc professors.
- **2000** – GENOMED, country's first JV between Institute (CBT) & Industry (Nicholas Piramal) to pursue pharmaco-genomics.
- **2001** – NCBS scientists sets up Avesthagen a plant genomics company.
- **2001** – GEAC approves Wockhardt's E PO.
- **2001** – NIH approves NCBS and Reliance Life Sciences as 2 out of 10 labs worldwide, for stem cell lines.
- **2001-** Drug Authority implements GCP (Good Clinical Practices) guidelines for clinical trials.
- **2001** – Millennium Biotech Policy, the first state level biotech policy, announced by Government of Karnataka.
- **2002** – Institute of Bioinformatics & Applied Biotechnology a jointly funded initiative between Government of Karnataka & ICICI commences academic program.
- **2002** – GEAC approves Shantha biotech's interferon Alpha 2b.
- **2002** – GEAC approves Bt cotton commercial planting.

5.1.5 The Biotechnology Policy in India

The business sector in India has been developed through planned effort using the implementation of policies through several five years plans. For the growth of any new industry, new infrastructure, plant and machinery, equipment and instruments, facilities for research and development, regulatory norms and facilities for development of the human resources for that business is absolutely important. It has been achieved through government initiatives in India and biotech is no exception to that.

The Indian Government started making investments in creation of infrastructure for biotechnology since 1985 by setting up a dedicated Central Department for Biotechnology.

The Department of Biotechnology (DBT) is the nodal agency for formulation of policy, promotion of R & D, international cooperation and manufacturing activities. In mid eighties, DBT focused on generating trained manpower & infrastructure development. The current focus is on genomics, proteomics, transgenic, stem cell research and product development. Having invested US $ 500 million towards R & D in National Laboratories and Centers of Excellence since its inception in1986, several products in agriculture, industrial and health areas are already in the market.

The Indian government on its part has been increasing the outlays for biotechnology over the past decade. The budgetary allocations have gone up by a tremendous amount from just 404 million Rs in 1987-88 to 1138 million in 1997-98 and to almost double the amount i.e. Rs. 2356 million in 2002-03. The central government is also planning to introduce additional venture capital funds in line with its **T**echnology **D**evelopment **F**unds (TDF) to promote small and medium biotech enterprises.

In addition to DBT, several other agencies in India also fund biotech research, although the others are not dedicated to funding only biotech research. Budgetary allocations for all these have gone up in the last decade.

For example CSIR has provided 9120 millions Rs. in 2000-01 as compared to 2351 million Rs. in 1990-91. and UGC has increased it from about 3495 million rupees to 14070 million rupees in the same duration.

Table 5.1 Budgetary Allocations of Major Funding Agencies in India (Rs. Millions)

Funding Agencies	**1990-91**	**2000-01**
Department of Scientific and Industrial Research **(DSIR)**	131.3	583.8
Department of Science and Technology **(DST)**	2588.9	7798.0
Department of Biotechnology **(DBT)**	655.0	1361.0
Indian Council of Agricultural Research **(ICAR)**	3236.0	13990.0
Indian Council of Medical Research **(ICMR)**	396.0	1470.0
Council of Scientific and Industrial Research (**CSIR)**	2351.0	9120.0
University Grants Commission **(UGC)**	3495.0	14070.0

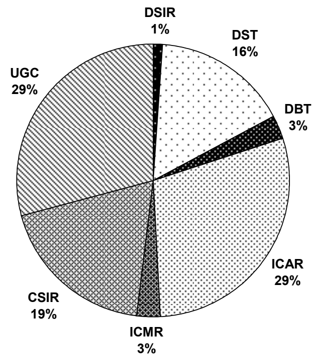
Source :Ministry of finance. Govt. of India.

These figures show that the government of India is committed to biotechnology as vital sector for India's future. All allocations have a rising trend.

The pie chart (fig. 5.2) of the funding distribution reflects the strategic direction provided by the government through each of the funding agencies. It is observed from the pie chart that for biotech education, (UGC-29%)

agricultural biotech research (ICAR-29%) Scientific and industrial research (CSIR-19%) and so on have been allocated.

Fig. 5.2 Percentage of Each Funding Agency for Biotech



This also shows the needs and priorities as taken up by the government initiatives. From the global and Indian biotech industry review it is clear that the bio-Pharma is leading sector and government wants to boost up agricultural sector which has a very small presence in the industry at present times (2005).

A regulatory framework is in place in India, to approve GM crops (Genetically Modified crops) and rDNA (recombinant DNA) products for human health. A government policy allows stem cell research in the country while having in place ethical guidelines. The Government is also inclined to adopt product patent regime. Indian Patents (second amendment) Bill was recently cleared by the Parliament. The key amendments in Patents Bill include 20-year patent term, emergency provisions and commencement of R & D immediately after filling of patents. Bill was in line with making country's patent law compatible with the provisions of WTO (World Trade Organization) and TRIPS (**Tr**ad**e-R**elated Aspects of **I**ntellectual **P**roperty Right**S)** [4]. While key aspects and relevant provisions of TRIPS, Paris

Convention[5] and Doha declarations[6] have been taken on board, available flexibilities are made use of to the maximum extent to safeguard national security and protect varied interests of the nation including public health.

More on Strategic Focus by the government can be read from the document -National Biotechnology Development Strategy Draft published by the Department of Biotechnology, Ministry of Science & Technology Government Of India and available for download at the website[7]. http://dbtindia.nic.in/biotechstrategy/Biotech%20strategy.doc

The readers are requested to refer to Comments on this policy by an NGO- Foundation for Biotechnology Awareness and Education[8] for highlights of critical analysis of the National Strategy for Biotechnology. The highlights relevant to Human Resources are discussed and analyzed in Chapter VI Human Resource Planning and Development Processes- An Critical Analysis based on factors.

In addition to the Central Government initiatives, several states have taken out their state specific biotech policies to boost the biotechnology sector in their respective states. The documents of these policies are also available on the respective government's websites for downloading purpose.

It can be said that "Biotechnology now has the potential to replace information technology as the engine of economic development for India."

After this analysis of Indian biotech on policy front it is necessary to have a look at the information and data about this industry so as to understand its growth pattern, strategic focus etc. so as to infer the requirements for human resource management issues for studying human resource planning and development within the context of present study.

5.2 Biotech Companies in India - Analytical Overview

The sources for this information presented in this section are BCIL, biospectrum and other government departments, information data collected through questionnaire survey, personal, telephonic and email discussions etc. Same have been used for the purpose of analysis by the researcher for the purpose of present study.

The time frame for which the data has been collected for analysis is from 2001 to 2003 and in the end the manpower data is presented for the sake of preparing analytical background for understanding of the Human Resource issues related to planning and Development.

Table 5.2 Biotech Industry 2002-2003 (India)

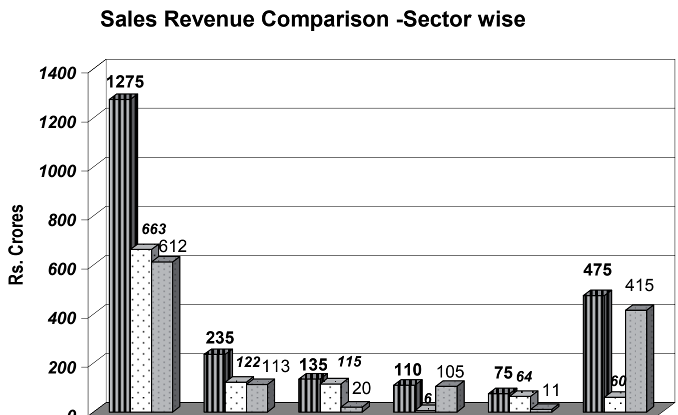
(including the Bio Suppliers)				
Segment	**Sales Revenues***	**Percentage share**	**Exports***	**Domestic Sales***
Bio Pharma	1275	55	663	612
Bio Industrial	235	10	122	113
Bio Services	135	6	115	20
Bio Agri	110	5	6	105
Bioinformatics	75	3	64	11
Bio Suppliers	475	21	60	415
Industry Size (total)	2305	100	1030	1276

Rs. Crores

The sales revenue in Rs. Crores for all the sectors such as Bio Pharma, Bio Industrial, Bio-Services, Bio Agri, Bioinformatics and bio suppliers is tabulated in the table 5.2 for the year 2002-2003

Comparison of sales revenue- sector wise is depicted in figure 5.4 for the purpose of analysis.

Fig. 5.3 Comparison of Sales Revenue-Sector wise (2002-03)



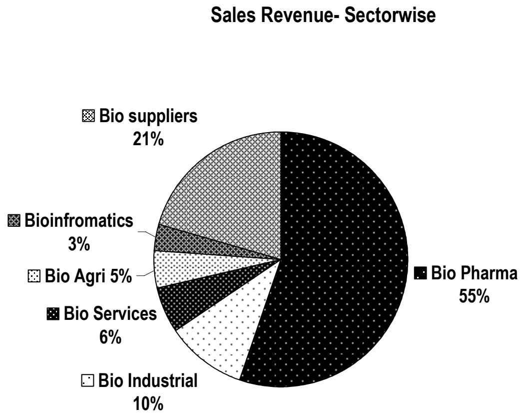
	Bio Pharma	Bio Industrial	Bio Services	Bio Agri	Bioinfromatics	Bio suppliers
Sales Revenues*	1275	235	135	110	75	475
Exports*	663	122	115	6	64	60
Domestic Sales*	612	113	20	105	11	415

Rs. Crores

The comparison made using fig 5.3 is very clear making the difference visible for different sectors. It also clearly brings out that Bio Pharma is leading and shows position of other sectors. The comparison of percentages brings makes the comparison visible.

The percentage of sales revenue sector wise is calculated and the percentages are represented using a pie chart in the figure 5.4

Fig. 5.4 Percentage Sales Revenue-For each Sector



From the pie chart analysis it is clear that **Bio Pharma is a leading sector in India** also. In the global overview of biotech business it was seen that Bio-Pharma is the leading sector (exhibit-1) and we can take that as a typical sector for detail study of operational aspects, leading to understanding of HR issues in the context of present study.

Exhibit 1: Bio-Pharma is leading in India
Bio Pharma is the leading sector in India. It can be presented as a typical sector for description of the operational aspects, organizational aspects like tasks knowledge & skill requirements as an example leading to HRP and D issues.

5.2.1 Regional Scenario

After the nationwide picture the regional level is projected to see the picture for analysis and drawing inferences. Table 5.3 and graphical representation will throw light on the regional contribution and contribution percentage of leading players countrywide.

Table 5.3 Regional Scenario

The Industry constitution in 2002-03 including Bio Suppliers

Business Class	Business (Rs. Crores)	% Share		Regions	Revenue (Rs. Crores)	%Share
Top 20	1366	59		**South**	899	39
Top 50	395	17		**West**	738	32
Others	544	24		**North**	668	29
Total Industry	2305	100		**Total**	2305	100

For the purpose of analysis two pie charts are drawn. They represent percentage share in revenue of business class i.e. top 20, top 50 and others in the total by fig. 5.5 and region wise percentage share in revenue by fig. 5.6

Fig 5.5 Business Class and Percentage Share in Revenue

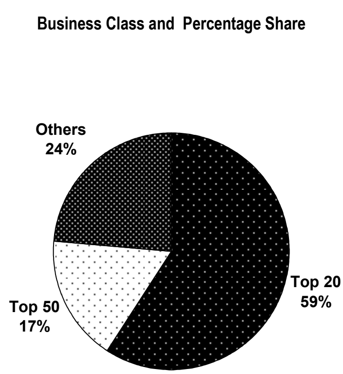
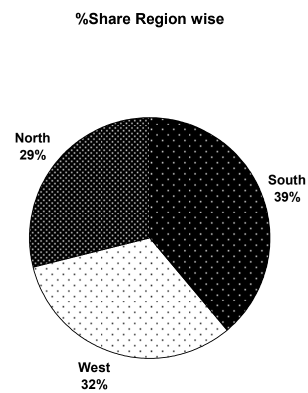


Fig 5.6 Region wise Percentage Share in Revenue



Inference from fig. 5.5 is clear that Top 20 have contribution which is about 60%, when one considers Top 50 the percentage dramatically goes down to 17 % and therefore the conclusion is that the top 20 companies are the best performers. We can refer back to the discussion in Chapter I for selection of the sample and corroborate that this inference reinforces the selection of the sample on the basis of performance, and the sample becomes more representative.

Fig. 5.6 indicates that there is a good regional balance as the percentage share is almost equal.

Table 5.4 shows the investment and patents pattern. It is clearly seen that the increase in investment in 2001-02 is 236% in 02-03 it is 26 % and the conclusion is that the investment trend in biotech is very good and substantially increasing. The patent scenario for India is also encouraging. This reflects the expectation of growth and subsequent creation of jobs, which increased the demand of workforce. Demand of workforce is one of the parameters of HR planning.

Table 5.4 Investments and Patents

Investment track			Patents		
YEAR	**Investment**	**Growth %**	**Patents**	**Filed**	**Granted**
FY2003-04	NA	NA	**Indian**	175	43
FY2002-03	635	26	**PCT****	70	20
FY2001-02	504	236	**Inter-national**	265	177
FY 2000-01	150	NA	**Total**	510	240

This tabulated information needs certain explanations which are given below in the form of notes.

Notes

- *Rs. In Crore
- **PCT (1970): The Patent Cooperation Treaty (PCT) permits an inventor to file what is called a PCT patent application. The PCT streamlines patent applications across several countries at once, and extends the grace period awarded under the Paris Convention to 20 or even 30 months. About 128 countries adhere to the PCT.

  More information available on the web site of Unites States Patents and Trademark office, (http://www.uspto.gov/web/offices/pac/dapp/pctstate.html)
- The revenues considered for the analysis are biotech products sales and service figures
- In the case of suppliers, revenues are the sales of equipment to pure biotech companies and also life science sector. There is very thin line of differentiation between biotech/life science equipment.

- The Agri segment analysis has included only the GM seeds. So the hybrid seeds business is not a part of the agribusiness sales values. The hybrid seeds market was close to Rs. 180 crore. Adding that the total Bio-agro market would be Rs. 290 crore.
- For all the ranking purposes, only biotech business has been taken into consideration. Wherever TURNOVER is mentioned it means, sales turnover from biotech.
- Women form a significant part of the workforce in research-intensive companies. They account for nearly 30 % of the employees in this sector. However, biotech companies, which are basically sales and marketing driven, are exceptions to the general trend of biotech companies having more women employees. Many of these companies are keen to induct women even in marketing, sales and technical functions, which require extensive traveling.
- In the regional table, the sales figures considered are the revenue generation of companies based out of the respective regions and not the sales(including suppliers) done in that region. As East has very little base, it has been included the same into North.

5.2.3 Human Resource Scenario in Indian Biotech

Against the backdrop of analysis and inferences discussed above, the manpower employed in biotech in India is tabulated in table 5.5

From the table 5.5 for investment and manpower it is clearly seen that there is a visible positive co-relation between the investment and the number of people employed in biotech business in India.

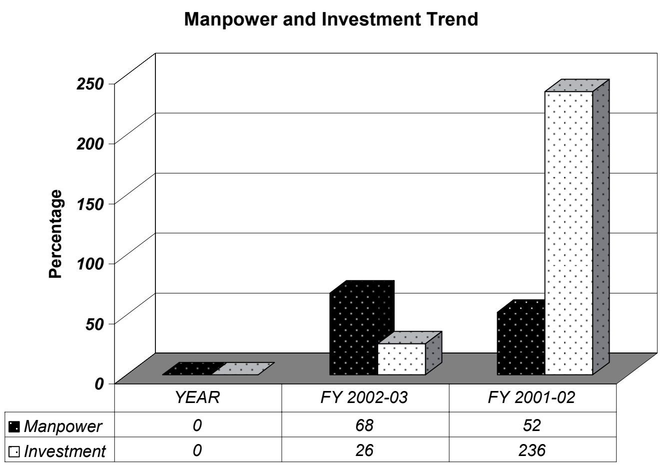
From the point of view of Human Resource Planning both the conclusions are important and useful and it can be said that growth in investment is an indicator of generation of more employment and demand for human resources increases in positive proportion of the employment opportunities generated.

Table 5.5 Manpower & Investment Growth - Year wise

		Manpower	Investment
YEAR	People	Growth %	Growth %
FY 2002-03	6400	68	26
FY 2001-02	3800	52	236
FY 2000-01	2500	---	----

The growth in number and percentage increase makes the point very clear.

Fig. 5.7 Manpower and Investment Trend (2001-02 & 02-03)



This speaks only about the number of employment, i.e. the number of people employed. For the purpose of planning and development the qualification of the employees, are also important. The distribution of the HR employed by qualifications, for the time period under consideration has been tabulated in following table no. 5.6.

Table 5-6 Manpower Distribution by Qualifications			
Qualification	**FY 2000-01**	**FY 2001-02**	**FY 2002-03**
Graduates and post graduates	1425	2165	3545
B. Tech / MBA	705	1025	1695
M. Tech /M.Phil	150	265	560
Ph. D.	70	130	285
Others	150	215	315
Total	2500	3800	6400

Analysis of the composition of the work force and year-wise change in that, if any, is also of interest for human resource planning on demand side. **It can be very clearly seen that for all the three years the demand for all types of workforce/manpower is on the rise.**

In the category Graduates and post graduates the number of employment is maximum for all the three years. Next category is that of B.Tech./M.B.A. Then it is M. Tech/ M. Phil, Ph.D. and least is others.

Table 5.6 is graphically represented for the purpose of analysis by fig. 5.8.

Next three charts represent pie charts for successive three years and make it possible to analyze the variables in question. These graphs were drawn after calculation of the percentiles for each year for all the categories for the sake of comparison and analysis.

Fig. 5.8 Year wise Manpower Composition by Qualifications

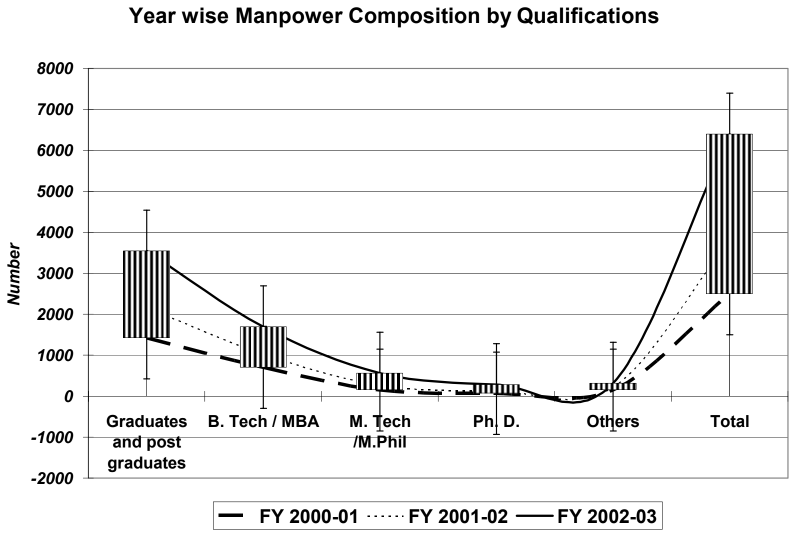
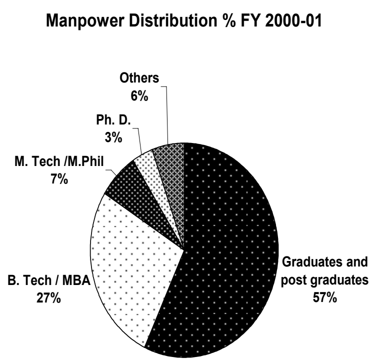


Fig. 5.9 Manpower Distributions % by Qualifications 2000-01



Graduates and Post Graduates=57%

B.Tech/MBA=27%

M.Tech/M.Phil=7%

Ph.D.=3%

Others-6%

Fig. 5.10 Manpower Distributions % by Qualifications 2001-02

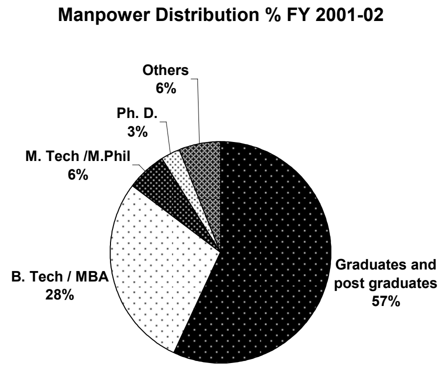
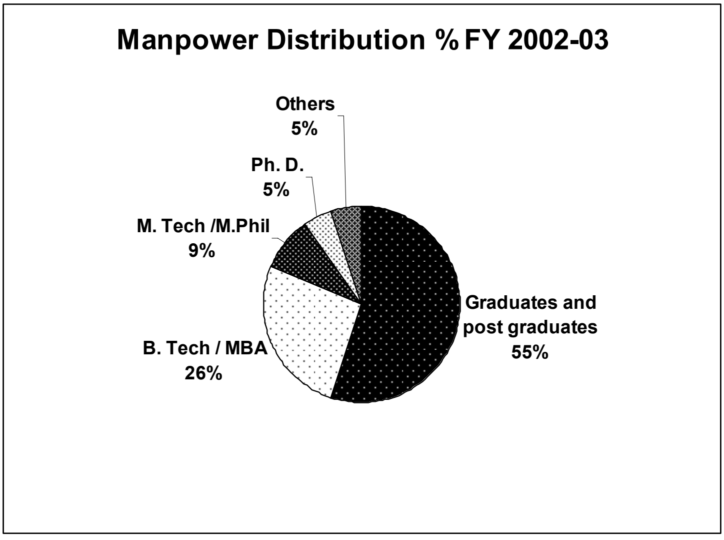


Fig. 5.11 Manpower Distributions % by Qualifications 2002-03



It can be very clearly inferred from pie charts for all the three years that the biotech workforce composition has following features though more features will come to light of the day during discussion of Knowledge and

Skill requirement, for the purpose of composition the broad basis of qualification is valid and enough.

Ex-2 Biotech Workforce Composition

1. Maximum Number of Employees is that of Graduates and Post Graduates (about 57 %)

2. Second Percentile Ranking is that of B. Tech /MBA (27%)

3. Third Category in Rank is M.Tech./M.phil 6 to 9%

4. Next in the line is others 4-6 %

5. Least % is Ph. D. 3- 5%

5.2.4 Biotech Work Force Composition

The results from above three pie charts viz. fig. 5.11, fig.5.12 and fig.5.13 are summarized as: Maximum number of employees is that of Graduates and Post Graduates (about 57 %), Second percentile ranking is that of B. Tech /MBA (27%), Third category in rank is M.Tech./M.phil 6 to 9%, Next in the line is others 4-6 %, and Least % is Ph. D. 3- 5%

These conclusions give us the inference that biotechnology workforce is mainly knowledge based workforce as the maximum number of them have to be graduates and postgraduates. This is concurrent with the statements in the global overview of the biotech and in the beginning of Indian Scenario, that biotechnology is knowledge based.

It is also noticed that the demand for people with qualifications at higher side, for example Ph.D. and B. Tec./MBA is increasing.

After this, brief description of sector wise activities viz. Bio Pharma, Agri Biotech, Industrial, and Services would help better understanding of the biotech business scenario from management point of view.

5.2.5 Bio Pharma - Medical Biotech

The Indian pharmaceutical market is growing exponentially. Its value in 1997 was US $ 3 billion and is expected to rise to US $ 9 billion by the year 2005. According to Mckinse study[9], Indian Pharma industry is poised to grow to an innovation led US $ 25 billion industry by 2010 with a market capitalization of almost US $ 150 billion from the current US $ 5 billion generic based drug industry. Vaccine market in 2001 was US $ 100 million and growing at 20% per year. Diagnostic market was US $ 200 mn in 2001. Bio therapeutics and diagnostics of which recombinant Hep B dominate medical biotech segment vaccine is the major product. Others include GCSF, EPO and interferon Alpha 2b. Human insulin was launched in 2003 along with Streptokinase, other vaccines and diagnostics.

The Indian government has granted marketing licenses for about 25 no. of recombinant protein therapeutics. Some of the recombinant products already approved by the Genetic Engineering Approval Committee (GEAC) are

- Insulin
- Interferon Alpha
- Interferon gamma
- Interleukin-2
- Gm-CSF
- G-CSF
- Hepatitis B vaccine
- Erythropoietin
- Streptokinase
- EGF
- Chymostrypsin

Traditionally India has been a very strong player in conventional generics due to established track record of process engineering skills and capability to set up comparable manufacturing units at a fraction of the capital cost utilized overseas.

Companies such as Shantha biotech, which started just one product, are now effectively using this experience to launch other products like plasminogen activators, interferons, sophisticated vaccines etc. Following the suit of globalization many multinationals like Monsanto, Pfizer, Uniliver, DuPont, Bayer, have set up their businesses in India. Eli Lilly-Ranbaxy 50:50 joint venture in India has been marketing a range of biotech products such as Humalog and Huminsulin for diabetes. Hoechst Roussel Vet has developed a cow abortion IBH vaccine in India. Chiron –Boehringer is setting up a vaccine venture in India.

5.2.6 Agri Biotech

India being the second largest food producer after China, offers a huge market for biotechnology products especially Agri biotech products. This, combined with excellent scientific infrastructure in agriculture, rich bio-diversity and skilled and low cost human power, make India a great force. Transgenics of rice brassica, moonbean, pigeonpea, cotton, tomato and some vegetables like cabbage, cauliflower etc. will complete field assessment and some of them would be ready for large scale production by 2005. More protein rich wheat with higher lysine content will be introduced in the farmer's field by 2003-2005. Nutraceuticals market stands out to INR 25000-30000 mn (US $ 532-638) presently as per Ernst and Young report. Genetically engineered seed market was worth an estimated $ 250 million from total seed market worth US $ 500 million in 2001. Marine resource development and aqua culture also hold a great potential with India having more than 8000 kilometers of coastline including Andaman and Nicobar and Lakshwadeep.

There is a presence of global companies in this sector too. US based Hicks Muse's proposal to take up 75% equity in India Seed Holding through its Mauritius subsidiary was cleared by the government. The company will bring forth foreign investment worth 35 million for production and marketing hybrid and improved variety of seeds. The Indian partner in this venture is Mahindra Hybrid Seeds, besides this Bayer functions in India through acquiring New Delhi based Pro Agro group companies.

5.2.7 Industrial Biotech

This segment is expected to show significant growth commensurate with the growth of the Biotech sector. Products include enzymes, bio-instrumentation and bio process equipment.

5.2.8 Services

An increasing number of large pharmaceutical companies are finding it difficult to conduct the entire drug discovery process in house. India on the other hand provides cheaper infrastructure. For example a biotech based therapeutic product costs $ 250 million and 10 to 15 years to reach the market. In India the cost of drug discovery research can be reduced substantially due to local norms and payment in rupees. This has given rise to contract research organizations specializing in drug discovery research services. Contract research services are largely focused on molecular biology, bioinformatics, genomics and stem cell research. Clinical research and trials are expected to grow exponentially over the next 5 years. Scores of large IT companies have already established bioinformatics units and Bangalore is bristling with bioinformatics startups. There are opportunities in India for data-mining, gene annotation, and the development of software interfaces. These require enormous computing power for which India has established its supremacy[10].

5.3 Case Studies- Indian Biotech Companies

For developing understanding of the human resource issues in the Indian scenario, case studies of few companies are also undertaken, as discussed in the Chapter I in the section on methodology. This has helped the researcher in developing micro level understanding of the dynamics and processes in the company. The focus of case studies is on developing understanding of resources, processes, products of the company which will help understand the issues of knowledge and skill sets along with other HR related issues. In the light of this information of knowledge and skill sets necessary to carry out the tasks by the workforce, the factors involved in planning and development of human resources for example, demand and supply pattern, recruitment methods and mode, training and development issues can be understood better. The case study material will be used along with questionnaire and interview survey for critical analysis of HRP and D in a separate chapters VI and VII.

For the purpose of case study, care is taken to include companies with active presence in Bio Pharma, Agricultural, Industrial sectors and discussion about the appropriateness of the sample has already been done in Chapter I and in the present chapter. The companies selected for micro level study of the topic under consideration were presented in table 1.1 and the four companies selected for case studies are presented as extract of that table, for ready reference

No	Name of the company	Sector	Rank	Code	Revenue*
1	Biocon	**1, 3**	**01**	**01**	**502.00**
2	Serum Institute of India	**1**	**02**	**02**	**491.00**
7	Wockhardt	**1**	**07**	**07**	**84.00**
16	Mahyco Monsanto	**2**	**16**	**16**	**54.00**

1=Bio Pharma/Health Care, 2= Agriculture, 3=Industrial ***Rs Crores**

The information obtained through the questionnaire survey for these selected 20 companies has been enriched for the purpose of reinforcing, validating the observations by way of writing case studies of few companies out of the total selection. This made it possible for researcher to look at the conclusions and the role players in a more rational way. The case studies for selected companies as described above are presented in the next sections.

5.3.1 BIOCON LIMITED.

Company History

Biocon Ltd. Is India's first biotechnology company and was established in the year 1978. The Company has built strong and experienced technology platforms based on fermentation processes. Biocon used its technology base to expand from industrial enzymes to bio-pharmaceutical products.

Business Model: Biocon has established the essential building blocks to become an **integrated bio-pharmaceutical company as shown Fig: 5.12**

Fig: 5.12 BIOCON, a FULLY INTEGRATED Bio-Pharma Company

Syngene- Drug Discovery

- Research & Development
- Molecular Biology
- Synthetic Chemistry

↓

Clinigene - Development

- Clinical Research
- Clinical Developments
- Clinical Trials

↓

Biocon-Commercialization

- Microbial Technologies
- Pharmaceutical Manufacturing Sales & Marketing

Syngene (Drug Discovery) and Clinigene (Clinical Development) with these two sister concerns **Biocon** is positioned to become a global player within the bio-pharmaceuticals space and has a fully integrated business model.

Major Achievements by Biocon Ltd.

India’s first biotechnology company, established in 1978 achieved a global leadership in specialty enzymes in 1979. Within ten years, in 1989 developed a proprietary technique, Solid State Submerged Mammalian Cell Culture, which is globally unique. Syngene, in 1994 became India’s first & largest Contract Research Company. India’s largest and only USFDA qualified producer and exporter of statins, in 1998. India’ first clinical laboratory was established by Biocon in 2000, which was accredited by College of American Pathologists (CAP).

In the year 2005 Biocon was India’s no. 1 biotech company with a global Biotech ranking of 16 as shown in the table 5.7

In the field of recombinant human insulin, Biocon manufactured clinically validated r-human insulin in India and has a largest plant in Asia for manufacturing the same at Bangalore. They have developed arrangements for global distribution of the same and also are developing oral insulin.

In the year 2003 Biocon established India’s first and largest Antibody Facility and provide a unique platform of proprietary products in Antibodies and Cancer Vaccines.

Analysis: The average revenue per employee has gone up by 2 mn. Rs. Benefit/Cost per employee has gone up from 6.2 to 11.6 which is almost double. Reduction in employee cost. Reduction is seen in employee turnover. Increase in Average PAT by 0.9 million.

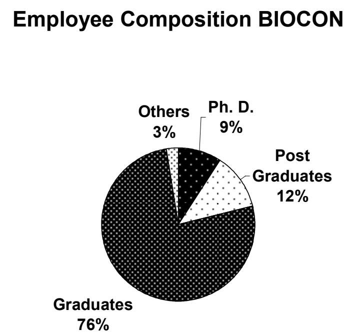
Table: 5.7 Biocon India – 16th in Global Top 20- Year 2005

Rank	Company	Revenue US $ m 2003	Net Income US $m 2003	Market Cap US $m as on 29 June
1	Amgen	8400	2260	68800
2	Genentech	3300	563	57500
3	Biogen Idec Inc	2300	875	21300
4	Chiron Corporation	1800	227	8400
5	Applied biosystems	1680	183	4500
6	Genzyme corporation	1580	104	10600
7	Sereno	1500	390	9900
8	MedImmune	1054	192	5800
9	Novozymes	950	123	2300
10	Gilead Sciences	868	72	1400
11	Biovail Corp	824	27	3000
12	Millennium Pharma	434	484	4200
13	Genecor International	380	16	968
14	Spracor	360	136	4500
15	Affumetrix	301	14	1900
16	**BIOCON** →	**120**	**30**	**1100**
17	Netkar	105	47	1200
18	Celera Genemics	88	82	824
19	ImClone Systems Inc	81	113	6500
20	Exelixis Inc	51	96	600

Source: BioSpectrum July 2004

Human Resource Scenario

FIG. 5.13 HUMAN RESOURCE SCENARIO-BIOCON LTD



65 Ph.D.s, 84 Post graduates, 536 Graduates, 18 others

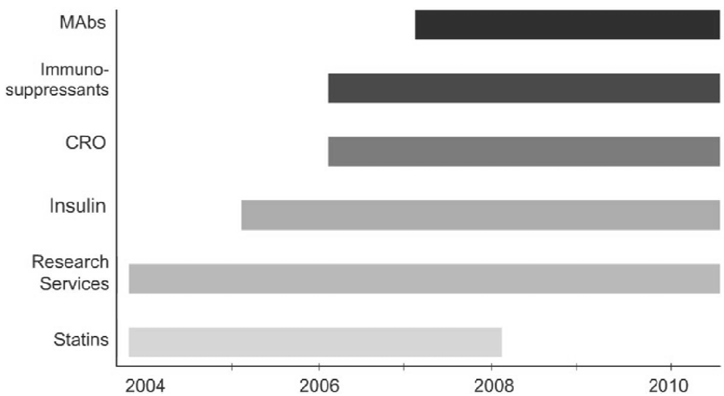
Table 5.8 Biocon - Employee Costs for 2003 and 2004 in Rs million

	2003 Rs million	2004 Rs million	Change Rs million
Total Employee costs	382.0	457.0	+75
Employee nos. (average)	663.0	867.0	+204
Avg Revenue per Employee	4.3	6.3	+2
Avg PAT per Employee	0.7	1.6	+0.9
Avg cost per Employee	0.6	0.5	-0.1
Employee Turnover	9%	7%	-2%

It suggests a good HRM for retention in terms of strategic competitive advantage.

Future Challenges In the bio pharmaceuticals arena Biocon has plans to face the future challenges. Fig. 5.17 shows strategic focus for future development of the company.

Fig. 5.14 Future Plans – Strategic Focus



Important Observations and Conclusions

The above study is useful for throwing light on micro aspects of Indian biotech scenario, as an example. It gives idea about employee costs and turnover and the growth drivers indicate the strategic retention policy of the company. The future plans indicate that company plans to focus on statins, research services, insulin, immunosuppressant and monoclonal antibodies. From this the manpower demand in terms of areas of operation can be estimated. From the tune of operations the number of employees of given qualifications, experience and competencies would be easily estimated. It can be said that at Biocon the HR function is now being handled in a strategic manner at least for retention. Form the difficulties in training and development area, the company naturally faces the same problems which are posed by Indian environment. As the skills and competencies have not been identified systematically the necessary vision for HR planning and Development is lacking. These problems are discussed more in details in the chapter where analysis of HR planning and development is discussed.

As written in the chapter III on operational details of Biotech Company, and from the details presented for BIOCON, it reinforces that

biotechnology is global and this company has its own specialty in the process within the framework of this progressive technology.

Conclusions

The case study provides the dynamics behind the success of the company. Integrated business model Drug Discovery – Development – Commercialization. Analysis of HRM suggests good HRM in terms of retention strategic competitive advantage in terms of retention, which is exemplary for companies all over the country. The difficulties faced in providing training even if the need was there, are same for all the industries and hence in the absence of systematic information about knowledge, skill sets and competencies there is lack of vision necessary for sound process of HR planning and development.

5.3.2 SERUM INSTITUTE OF INDIA LTD.

Company History

Serum Institute of India is basically an organization concentrating on vaccines and other biologicals, for example pharmaceuticals such as Haematinics, Calcium Supplements, Digestives, Anti-diarrhoeals, Hormones, etc. They created another facility, which was incorporated in July 1993 as ‘Serum International Ltd.’. Serum International Ltd. also markets, research based products from Serono, world leaders in fertility products.

Important Mile Stones:

The information presented below provides focus of the company in terms of the development of the products. It is vaccines, and that Serum is one of the large exporters of vaccines the world over.

1967-"Operations started with manufacture of Tetanus Antitoxin followed by Fluid Tetanus Toxoid. "

1974-"Triple Antigen (Diphtheria-Tetanus-Pertussis) Vaccine production commenced."

1972-"Large-scale manufacture of Adsorbed Tetanus Toxoid undertaken."

1977-"Autonomous scientific wing, Serum Institute of India Research Foundation established."

1979-"In response to urgent requirement of vaccines for India's EPI, giant Blending Vessels indigenously fabricated."

1980-"First-time-in the-world collection of equine serum by simultaneous and continuous plasmapheresis using IBM Computerised Cell Separator."

1981-"Manufacturing of life-saving Polyvalent Anti-Snake Venom Serum effective against four poisonous snakes commonly encountered in India commenced."

1982-"Introduction of Anti-D Rho Immunoglobulin, Iyophilised and tested on Autoanalyser."

1984-"A 2500- litre Blending Vessel, largest in the world for DTP vaccine, successfully fabricated and commissioned."

1985-"Hi-tech plant set up for large-scale manufacture of Human Albumin from human placenta."

1986- Recognition:"The film 'Snakebite' awarded 'Best Professional Film Award' at ninth International Film Festival in U.S.A. Followed by two more international awards in 1987 and 1989."

1988-"Product availability expanded to include range of Fertility Products of World Leaders, Serono of Switzerland."

1989-"Manufacture of M-Vac (Measles Vaccine) using E-Z Strain of virus

on Human Diploid Cells for the first time in India."

1991-"Anti-snake Venom Serum, incorporating venoms from snakes in Central African Countries introduced."

1997-"Commencement of export of Anti-cancer products."

"Use of Modular Laboratory meeting international GMP requirements"

1996-"Use of Automatic printing and Labelling Machine, use of Automatic Inspection Machine (screening) for liquids in ampoules and vials."

1994-"Commencement of export of vaccines to UN agencies."

1993-"Manufacture of MMR Vaccine and MR vaccine for the first time in India." "Launch of Serum International Limited."

1992-"Manufacture of Rubella virus vaccine (monovalent Rubella vaccine) for the first time in India."

1998-"Export of vaccines crossed over to 100 countries"

1999-"Serum Institute recognized as the largest producer of Measles and DTP vaccines in the world"

2000-"One out of every two children in the world vaccinated by Serum Institute's vaccine"

2001-Launch of indigenously manufactured Recombinant Hepatitis-B vaccine 'GeneVac-B'

2002-Launch of BCG vaccine

Important Observations

Serum Institute of India Ltd is the largest exporter of vaccines and immuno-biologicals from India. Across the globe its products are exported to 138 countries. It has gained worldwide recognition as a reliable source for quality vaccines, for the global vaccination programs.

Serum Institute has revenues of approximately Rs 491 crore from the

sale of biotechnology products in 2002-03. Out of this, exports were to the tune of Rs 378 crore, or 77 percent of its products are exported. A subsidiary company of Serum Institute, Serum International Ltd, is known to handle the sale of imported products as part of the company's agency operations. It is estimated that the agency operations accounted for the remaining Rs 64 crore of the total Rs 555 crore business reported by both the companies jointly in 2003-04.

The companies have a marketing alliance with Serono of Switzerland and technical arrangements with a number of American and European majors.

Human Resources, Practices and Strategic Directions

Serum Institute has policy to secure and retain only the best in terms of human resources, in terms of equipment and technology, in terms of materials and consumables.

The number of employees engaged in research has increased from 138 in 2002-03 to 182 last year. The employees in the manufacturing division also increased from 1095 to 1210 during the same period. In all, Serum employs 1,930 people, which had increased from 1,715 in the previous year.

Major Departments and Activities

Quality Assurance: Validation studies are mandatory for all equipment, all production processes and for analytical procedures in Quality Control. There is continuous monitoring of ancillary services such as water quality by LAL test, air-borne particulate matter by Met-one / Climate particle counter, live organism detection by air sampler, disinfectant efficacy, steam quality testing, air conditioning, refrigeration, sterile room integrity, and environment by settle plates and using other methods as per current GMP (cGMP- refer appendix III) requirements. Spot checks are also

instituted. Physical, chemical and biological methods are used to perform validation for the ovens, autoclave and tunnel. The data on each equipment, in the form of Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) is maintained in the respective departments.

The quality assurance protocol covers raw materials testing, in-process control and finished product checks. Certain testing procedures like the dermonecrotic test on Pertussis vaccine are carried out, though they are not mandatory.

The manpower factor is stringently governed. Each microbiologist, each pharmacologist and each chemist in the Q.A. team is hand-picked, according to the director HR. Twenty-two of them are F.D.A.-approved testing experts and thirty-two are production Experts. Their schedule of training included visits to the leading laboratories of France, U.K., U.S.A., the Netherlands and Croatia and they frequently attend WHO workshops.

The Q.A. Cell is engaged in several profession-related activities: It also has an exhaustive reference library for disseminates information via audio-visual aids, consults with international experts, gives training in Production and Quality Control to foreign UNICEF sponsored candidates. The QA cell also conducts orientation programmes for officers from Government regulatory agencies.

'Serum Institute of India Research Foundation'

Serum Institute has more focus on its Research and Development function. Within the span of ten years there was a record of product development and indigenization of processes. In 1977, a separate autonomous body, **'Serum Institute of India Research Foundation'**, was instituted. The Foundation has a group of highly qualified, intensively trained scientists. They interact on an ongoing basis with scientists and academicians from other institutions in India and abroad. Personnel from the

Research Foundation regularly attend international conferences and workshops, and eminent personalities are periodically invited to India for exchange discussions and technical and research consultations. The Research Foundation has been recognized in India and abroad.

Important Observations

Serum Institute of India commenced with a beginning of Tetanus Antitoxin and has now emerged as the world’s largest manufacturer of Measles Vaccine and DTP group of vaccines. (at least one of two children born has been administered with Measles vaccine or DTP vaccine manufactured by Serum Institute)

Serum Institute went on to launch, Polyvalent Anti-Snake Venom Serum, Measles Vaccine on Human Diploid Cells, Measles, Mumps and Rubella Virus Vaccine, Polyvalent Anti-Snake Venom Serum (Central Africa), Mumps Virus Vaccine, Measles and Mumps Virus Vaccine, Measles and Rubella Virus Vaccine and several other products that attest to its seriousness of purpose.

Some of the products in the pipeline are Hepatitis B Vaccine, Hepatitis B-DTP Combination Vaccine, BCG Vaccine, Rabies Vaccine (Human Diploid Cells) and Rotavirus Vaccine.

Progressively, Serum Institute eliminated India’s dependence on imports for several product lines.

Strategic Vision - Beyond 2000

The company is now nation's leading manufacturer of both DTP and MMR group of vaccines. Serum is classed as world players with their vaccines being used in 138 countries across the globe.

Serum Institute plans to continue to share its philosophy of care across many more shores. One major area of concern is the endeavour to prepare more heat stable vaccines. These would be of great value in Indian,

and in other tropical climates where dependence on the 'cold chain' is a current constraint. The breakthrough could come by using newer delivery systems in vivo for ensuring the presentation of the vaccine to the cells of immune system for stabilizing and releasing the antigen during an extended period of time.

Apart from making a recombinant Hepatitis B vaccine, the work on quadruple vaccine involving Hepatitis B with DTP is complete. Work is on to combine this with Haemophilus B vaccine to make an effective Pentavalent vaccine.

A liquid adsorbed Rabies vaccine has been made in HDC to give a stable, reaction-free and highly immunogenic vaccine. On the DNA vaccine front, work is on for developing a DNA Rabies vaccine. Also, a novel peptide vaccine for measles is being developed. Research and Development is on for a vaccine against AIDS.

Amongst other products developed under the Research programme are Haemocoagulase, Pygeum africanum and Percutaneous BCG vaccine for treatment of bladder cancer.

Serums Diversification plans include advances in a wider range of vaccinology including Molecular Biology and Recombinant DNA (rDNA) Technology, Protein Biochemistry and formulation of antigens containing newer excipients, adjuvants for better performance of the vaccines and delivery systems, lyophilisation on a vast scale. This will create wider avenues of growth and demand for qualified human resource.

Conclusions

- Strong Research and Development Focus.
- Quality in all Processes including Human Resources
- Training and Development for maintaining quality and productions standards of international requirements. Methodology for that is

national and international workshops and programmes and sharing with institutions.

- Careful selection of Manpower is of strategic importance. The organization is technology dominated and the techno-structure provides the leadership at this stage of the business cycle. The development aspect is taken care of by sending people for national and international programs and creating a platform for sharing knowledge with research institutions.
- Future plans with strategic focus will create demand for qualified human resource.
- Company at present has been managing HR function strategically for retention and has reinforced HRD by recruiting experienced people to handle that function separately.
- Lack of systematic information about knowledge, skills and competencies reflects neglect in HR planning as a long term factor strategic planning.

5.3.3 WOCKHARDT LIMITED

History of the Company

The Indian company, Wockhardt Limited, was founded in 1960, and today claims its place amongst the country's top research and technology oriented pharmaceutical companies. Wockhardt has subsidiaries in the United States, the United Kingdom and Brazil, and majority-owned companies in South Africa and Mexico. The company also has marketing offices in Africa, Russia, Central Asia and south East Asia.

In 2003, the company launched Wosulin, a recombinant insulin product. In doing so, Wockhardt became the fourth company, and first Asian manufacturer, to be able to offer the product. Wockhardt has identified

biopharmaceuticals as a major developing market area, is selling generic biopharmaceuticals in the US and EU. Wockhardt's 53% of international business is from Europe and US as can be seen from following figures,

1994	10% of sale from Europe and US
1999	20 % of sale from Europe and US
2005(half 1)	64% of sale from Europe and US

- Sales $ 300 mn
- R & D spending @ 8% of annual turnover
- Market Cap $ 1.3 billion

Geographical Revenue Split

- Europe 41 % USA 11% India 36% Rest 12%

The above shows increasing international focus

US & EU Business constitutes more than 50% of total revenues.

Major Activities and Achievements, Recognitions etc.

Wockhardt has capabilities developed 'from concept to market" and is one of the Leading Indian Pharmaceutical and Biotechnology company. It is the only pharmaceutical company in India to be selected as Business Super Brand by the Superbrands Council- Internationally reputed organization spread over 45 countries. This a recognition for offering consumers emotional and tangible benefits.

Workforce Scenario

3500 employees are across locations in India and abroad and 500 employees are in US & Europe with features like R & D and Manufacturing Competitiveness, Biopharmaceuticals and Generics as product lines, Regulated Markets in India and Rest of the World.

A New Chemical Entity is generated through R and D which is

multidisciplinary in nature covering genetics and biotechnology. For this activity a team of human resources having multidisciplinary skills is available. IPRs are also created on successful implementation of projects. There 350 scientists with 100 Ph.D.s and 150 applications have been filed for patents. Wockhardt has 3 patents in the area of biopharmaceuticals.

MANUFACTURING CAPABILITIES and Products

- Strategically located manufacturing facilities in UK & India
- Approved by major regulatory authorities including US FDA

steriles-Vials, Ampules, Cartridges, lyophilized products, Cephalosporins, **Biotech-**: 3 major expression systems: yeast, e-coli, mammalian cell

Formulations: vaccines and non-vaccines

Oral: Tablets (including effervescent), Capsules, Liquids

Topical: Creams and Ointments

Important Observations

Wockhardt is already marketing its products to seven countries. And has plans to market to 19 countries by 2006. It has 20 registrations for Pharma products in India and over 40 are in the pipeline. These will also be registered in European Union and the United States. To meet this global need it has bio-manufacturing facility, biotechnology plant and pilot scale plants. The six biotech products developed by Wockhardt are rhu Insulin, r Erythropoietin, Hepatitis B Vaccine, Interferon alpha 2B, Glargine, and G-CSF. to summarize one can say that it is a Largest Indian generic company, 2nd largest in the hospital business amongst top 10 generic companies, and has US FDA approved comprehensive manufacturing capabilities. The company expects to continue to outperform the industry growth rate and key growth drivers are Biotech, Diabetalogy and Nephrology. Indian business is

expected to grow @ 12% + This implies that Wockhardt's has good demand created for qualified human resources in the field of bio Pharma, in all categories viz. R and D, Manufacturing and related functions and Marketing, not only in India, but across the globe

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5.3.4 MAHARASHTRA HYBRID SEED COMPANY LTD.

Company History:

Mahyco was founded in 1964, by Dr. Badrinarayan R. Barwale who is a Winner of the World Food Prize-1998. It is a private company in India which produces and markets hybrid Sorghum, Pearl Millet, Sunflower and Wheat and first company in the world to successfully commercialize hybrid Cotton based on GMS /CMS. In 2002 it became the first Indian company to be allowed to commercially grow and market Bt cotton- which is India's first Genetically Modified crop.

Major Departments and Activities

It has a Network of more than 100000 farmers in 33 production centres of India. Mahyco has 8 state-of-art Processing units with in-house Quality Assurance facilities. It is a Member of ISTA (International Seed Testing Association) under Article 1V (C) of the ISTA certificate. A strong R & D infrastructure developed near Jalna (Maharashtra). This is an ISO 9001 company with largest multi-locational ISO certification..

Mahyco Research Center is built on a 110 acres with buildings for Administrative offices, Research Laboratories, Greenhouses etc. near Jalna (Maharashtra). This description makes it easier for the understanding of the skill sets required for working at Mahyco and thus we can say that this infrastructure also tells us about the type of HUMAN RESOURCE necessary for agricultural biotechnology being practiced at the company.

DNA Sequencing LAB

Equipped with Perkin Elmer ABI Prism 377, automated DNA sequencer, up to 96 sequences can be made in one run. Up to 800 base pairs in a DNA sequence can be resolved in each sequence. Virus sequences, gene sequence analysis, novel gene sequences, quality control of new constructs are undertaken.

Molecular Virology LAB

Mahyco has an in house facility for detection, identification and molecular characterization of plant viruses (Geminiviruses, TOSPO, ILAR and Poty groups) of economic importance. It has Virus resistance screening and Identification of prominent genotype for product development. Diagnosis of plant virus diseases by using Electron Microscopy and Serological properties can be done here.

Applied Molecular Genetics & Molecular Biology LAB

Here it is possible to study the plant pathogen interactions at the molecular level and apply the results in developing durable and / or enhance disease resistance. Microbial genomics programme to identify novel agronomically useful genes or gene products from micro flora native to India and apply such identified gene(s) or gene products in developing new tools and technologies for crop improvement. Developing molecular markers for enhancing breeding programmes and to characterize genetically Mahyco's germ plasm is a routine. The lab is having fermentation and associated facilities to develop indigenous, cost effective fermentation technologies to produce agriculturally important microbial metabolites.

Bio -Technology LAB

Gene discovery projects for useful agronomic traits such as drought resistance and insect resistance antibody mediated and gene silencing strategies for pathogen control, alternative male sterility system.

Plant Transformations

Transformations and molecular analysis of transgenic plants are undertaken. Routine Genetic Transformations of many different crops including Paddy, Sorghum, Tomato, Brinjal, Okra etc.

Plant Disease Clinic

Isolation and Identification of Pathogen from infected samples is carried out here. Detection and recognition of plant disease is also undertaken along with Screening for disease resistance in seeds etc.

Green House Facility

6500 sq. meter of climatically controlled Greenhouses built to specifications of Govt. of India, Biotechnology Department. Experimental trials and breeding programs with transgenic Cotton, Sorghum, Rice, Brinjal, Tomato, etc. are undertaken.

Seed Testing Laboratory

This laboratory is capable of analyzing Isozymes, Seed Health, Germination, Physical, chemical characteristics, qualities such as taste, flavor and acceptability of grains. Experimental trials and breeding programs with transgenic Cotton, Sorghum, Rice, Brinjal, Tomato, etc. undertaken. The production, processing and packaging of seeds are done as per stringent quality assurance norms.

Mahyco's Seed testing lab (QC) has been granted the status of Member Laboratory of the International Seed Testing Association (ISTA), Zurich, Switzerland since 1999. Seed testing for genetic quality is necessary to certify a genetically pure seed. Seeds that do not contain any other seeds of the same crop or other species is highly desirable. Among other tests, isozyme analysis is an important tool to determine genetic purity in seed lots. We employ this technique for rapid identification of undesirable inbred seeds in F1 seed production program. We carry out isozyme analysis in seed

quality testing. Sorghum, bajra, maize, sunflower, paddy, tomato, cantaloupe and chilli are some of the crops that we routinely subject to this test.

Mahyco Life Sciences Research Centre (MLSRC), at Dawalwadi near Jalna is one of Asia's advanced seed industry R&D establishments and is equipped with state of art labs for seed health, molecular biology, cytogenetics, pathology, entomology, molecular virology and plant transformation. The germplasm preserved is one of the most extensive and diverse in the land. Best multi- disciplinary talent, trained nationally and internationally work in the centre. The company carries out its research at 6 centers all over the country. In addition, the multi-locational crops performance testing is presently carried at 16 different centers in the country.

Quality Assurance

The production, processing and packaging of seeds are done as per stringent quality assurance norms. **Seed testing lab** (QC) has been granted the status of member lab. of the International Seed Testing Association (ISTA), Zurich, Switzerland since 1999.

Production Centers

More than 100,0000 grower farmers, 29 **production centers**, a million quintals of seed processing capacity at 14 processing plants and more than 25000 quintals of dehumidified storage for sensitive seed material are highlights of Mahyco's truly huge infrastructure. The production and the processing network is supported by a well developed all India marketing network consisting of more than 5000 sales outlets.

Awards for Excellence

Mahyco has received several awards for the pioneering role in developing the private seed Industry in India.

1989 – 'National award for Research & Development' Presented by the ministry of science and technology.

1990 - International Seeds and Science Technology (ISST), and the Federation of Indian Chambers of Commerce and Industry awards for notable contribution to the seeds industry in India.

1996 - Company Chairman B. R. Barwale, was named an honorary Life Member of the Federation of International Seedsman (FIS) for his pivotal role in the development of the private seed industry in India and for his dedicated service to national and Inter national seed trade organizations.

1998 - The World Food Prize for outstanding achievements in the enhancement of the world's food supply was awarded to B. R. Barwale by the World Food Prize Foundation, U.S. A

2001 - Chairman Shri B. R.Barwaleji was honoured with "Padma Bhushan" on the occasion of the Republic Day Celebration on 26th January, 2001. This award is in recognition of his distinguished services of high order in the field of Trade and Economic Activity.

- First National Award for Bio-tech Product Commercialization in May 2003.
- National Award for Research and Development – 1989
- International Seeds and Science Technology (ISST) Award – 1990

FICCI award for notable contribution to Indian Seed Industry -1990

Future Challenges for Mahyco

Strategic Focus

Food for everyone: Indian agriculture faces tremendous challenges of producing enough food for its growing population. This must be accompanied on same or declining land mass. There is a continuing need to

increase food production in the developing countries. And this increase has to come from increased yields from major crops grown on existing cultivable lands. Many approaches will have to be deployed simultaneously to double India's food production by 2025 and Mahyco is a leader in R and D for these field operations in the private sector.

Pest and Insect Control: Insects not only cause direct loss to the agricultural produce, but also indirectly due to their role as vectors of various plant pathogens. In addition to direct losses caused by insects, there are additional costs in the form of pesticides applied for pest control, currently valued at US $10 billion annually. In crops such as pearl millet, sorghum, pigeon pea, chicken pea and groundnut grown under subsistence farming conditions in the developing countries, the losses due to various biotic and abiotic factors have been estimated to be over US $ 2 billion annually. Massive application of pesticides results in adverse effects on the beneficial organisms leaves pesticide residues in the food causing environmental pollution. In addition, the target pests evolve and become resistant to the pesticide, requiring higher volume of spray for control. As a result, the chemical control of pests is under increasing pressure. There is a greater need to develop alternative or additional technologies, which would minimize pesticide use, and provide adequate crop protection for sustainable food, feed and fiber production in the future.

Besides the insect pests, diseases caused by Viruses, bacteria, fungi and other micro organisms are emerging and pose greater threats to Indian farming community. A number of conventional and biotechnological methods that are now available make it possible to transfer, track, isolate and study specific genes for specific traits.

With the advent of genetic transformation techniques, it is now possible to insert genes in plant that provide a unique trait. Technologies are now borderless, genes from bacteria can be transferred to plants or genes

from unrelated plant species can also be transferred. For example, gene from bacterium such as Bacillus thuringiensis (Bt) has been identified and through plant transformation introduced in crops for pest control on a commercial scale.

Important Observations

(i) Mahyco has invested considerably in its R&D during 1998 to 2003.

(ii) Genetically engineered cotton containing the 'Cry1Ac' gene from the bacterium Bt has been brought in the country. The **Bt cotton** hybrids which contain the 'Cry1Ac' gene, makes it resistant to the cotton bollworm pest that inflicts heavy damage to the crop all over India. As this is a genetically enhanced product, regulatory approval is required from Govt. of India. The clearance was given by the Genetic Engineering Approval Committee (GEAC) under the Indian Ministry of Environment and Forests (MOEF).

(iii) Plans to develop genetically modified Rice, Wheat, Sorghum, Brinjal, Tomato etc. Mining microbes and plants for agronomically useful genes from indigenous sources native to our country to be introduced in crop plants.

(iv) Heavy investment in the R and D, but the commercialization of products has to undergo long waiting period and this makes the activity prone to economic losses.

This case study clearly brings out the aspects of agricultural biotechnology skill sets required by this industry which has international association for Bt cotton with a giant company Monsanto. The skill sets can be understood from the R& D profile of the company and is seen that they are as have been listed in the questionnaire. The strategic focus tells about the HRP and D aspects of this growing company.

The strategic focus which has been described in more details, as it describes some of the operational details of agricultural biotechnology. Though the focus of present study is on bio Pharma as an example, the description of operational details is in order. It can be seen that the biotechnology techniques used are same, and as mentioned in chapter II the description related to raw material and consequent changes using these techniques differs in the results and intermediate descriptions are similar.

5.4 Conclusion

Indian scenario has been presented in the context of global biotech and it is seen that Several American and European companies are facing resource constraints. For increasing productivity one way for them is to develop collaboration with companies with those resources at a lower cost. With its abundant high quality-low cost manpower, India is emerging as a partner of choice.

India’s major biopharmaceutical companies are now accelerating efforts to get bioequivalent versions of patented, well-characterized recombinant proteins onto the market before 2005. The small biotech companies are focusing on innovative research, and are picking niches where there is little competition. Bioinformatics companies are other players who are benefiting from an intellectual property driven model.

The four case studies presented are representative, for knowing the biotech companies in terms of products, operations, market position and HR scenario, for example Biocon, showing HR parameters as an illustration of results good HR practices for retention. There is general absence of systematic information about knowledge skill sets and competencies required in biotech business. This portrait of Indian scenario has provided sufficient backdrop for understanding description in chapter III Biotech Businesses- Operations and Organization, HR management in biotech

companies in India, and Chapter VI Human Resource Planning and Development in biotech companies.

ENDNOTES

[1] http://www.biotech-india.com/biotech_industry.htm

[2] http://www.ey.com/global/download.nsf/India/BioTechRprt2004 /$file/BiotechRpt2004.pdf

[3] http://www.apidc.org/

[4] http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

[5] http://www.wipo.org/treaties/en/ip/paris/

[6] http://www.worldtradelaw.net/doha/dohatexts.htm

[7] http://dbtindia.nic.in/biotechstrategy/Biotech%20strategy.doc

[8] http://www.fbae.org/channels/views/comments_on_biotech_policy.htm

[9] http://www.smibusiness.com/marketsegmentationimp.html

[10] http://www.hinduonnet.com/fline/fl2201/stories/20050114002909500.htm
Frontline, Volume 22 - Issue 01, Jan. 01 - 14, 2005, India's National Magazine from the publishers of THE HINDU

Chapter VI
Demand for and Supply of HR
-in Selected Biotech Companies-

6.0 Introduction:

A detailed theoretical framework based on conceptual analysis of Human Resource Management was presented in chapter no. III. As has been detailed therein, HRM is considered as a process and procedure that tries to achieve 'Right People in Right Position and at Right Time'. This process includes five activities, viz. HR Planning, Staffing, Training & Development, Performance Appraisal and Compensation. As has been decided in the scope of this study, activities of focus for the present study are related to Human Resource Planning and Development in biotech businesses.

Almost all businesses demand human resources, and in the atmosphere of globalization, along with technological resources, human resources have become very important. This is because, for organization of operations in a competitive manner, trained and skilled human resource has a unique role. The role is that of deciding and implementing strategy and getting the operations done as per regulatory norms at optimized cost. This explains the reason for special demand of human resources. In the technology intensive businesses like biotechnology while forecasting the demand, the tasks to be completed for achieving the objectives of the business provide important parameters. These have been explained in detail in chapter III along with specific knowledge and skill sets required. This information provides a basis for estimation and forecasting of demand for human resources, keeping in mind the business model and scale of operations. For the purpose of analysis and understanding of issues involved in forecasting the demand for human resources, the methodology employed has been explained in chapter I. To restate the methodology

briefly, it can be said that the case studies provided a canvas of Indian biotech scenario, and using the information about the total Indian biotech companies in India a sample of twenty companies was selected for in depth study. Case study of four companies out of these 20 has already been presented in chapter V. Over and above this, a survey questionnaire was also administered to all the twenty companies including those of which the case studies have been presented. Copy of the questionnaire administered for the purpose of enquiry has been provided in appendix I. The responses to the questionnaire and discussions with managers of selected biotech companies forms the basis for data presented, discussion and analysis presented in the following sections of the chapter VI and chapter VII.

6.1 Forecasting Demand for Human Resources

Forecasting demand for Human Resources implies **how many people with what abilities the company will need in a foreseeable future to remain in operation.** It is seen that the forecasting is based on biotech advances in terms of growth of the company and in terms of Sales and Manpower number. Please refer to table no. 6.1 showing sales in Rs. Crores and change in manpower number for each company, for the years 2002-03 and 2003-04.

Fig. 6.1 Manpower Numbers for two years for each company

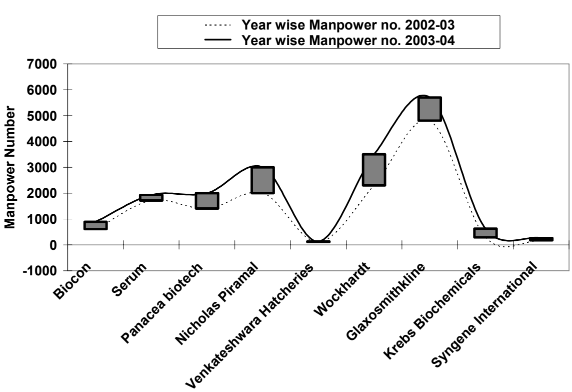


Table 6.1 Sales* in Rs. Crores and Manpower Number for two years for each company

Company Name	Code	Manpower Number		Sales in Rs. Crores	
		2002-03	2003-04	2002-03	2003-04
Biocon	**1**	600	892	**254.34**	**502.62**
Serum	**2**	1715	1930	**400.00**	**450.00**
Panacea biotech	**3**	1400	2000	**272.09**	**263.54**
Nicholas Piramal	**4**	2000	3000	**1017.22**	**1293.38**
Venkateshwara	**6**	110	135	**367.00**	**385.00**
Wockhardt	**7**	2300	3500	**765.79**	**863.44**
GlaxoSmithKline	**8**	4800	5700	**1148.21**	**1191.68**
Krebs Biochemical	**13**	290	625	**935.10**	**1091.20**
Syngene International	**18**	172	265	**26.25**	**38.48**

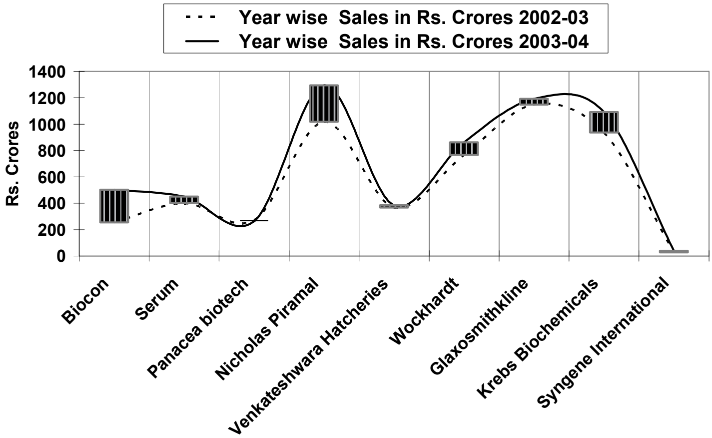
**Total Sales for the year*

The inferences with the help of these two graphs Fig: 6.1& Fig: 6.2 are

1) In the case of each company the number of manpower or workforce employed is on the increase.

2) The increase is substantial and corresponding increase in sales figure is also seen.

Fig. 6.2 Total Sales in Rs. Crores for two years for each company

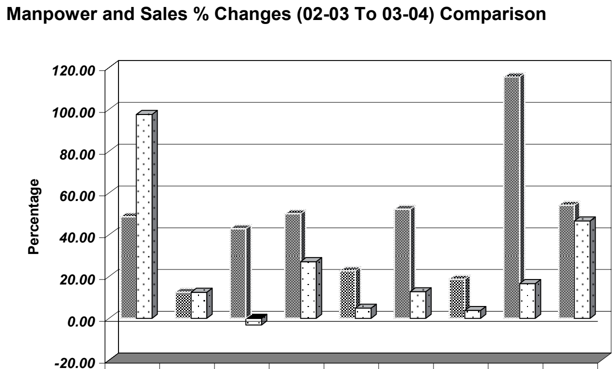


This shows the trend that growth in sales turnover of a company is positively related to growth in manpower.

For the purpose of drawing inferences the percentage changes in Manpower and Turnover for these companies, for the same years, are graphically represented. It provides more objectivity for drawing inference. That is represented in figure 6.3 and can be observed and inferred that with the increase in sales there is increase in manpower. A peculiar observation is noted here that in case of Panacea biotech, in spite of 42.86 % increase in Manpower (in 2003-04 as compared to 2002-03) the sales have been reduced by 3.14 %. **This is what indicates that we have to analyze the category wise requirement of manpower by the companies.**

An Interesting fact supporting this statement is that Panacea has unfilled positions in marketing and sales, which is reflected by their advertisement for these positions and response to the questionnaire. Not having enough manpower necessary for marketing is one of the major reasons for shortfall of sales as explained above.

Fig. 6.3 Manpower and Sales % Changes (02-03 to 03-04) Comparison



	1	2	3	4	6	7	8	13	18
Manpower %Change	48.67	12.54	42.86	50.00	22.73	52.17	18.75	115.52	54.07
Sales %Change	97.62	12.50	-3.14	27.15	4.90	12.75	3.79	16.69	46.61

1. Biocon, 2. Serum Institute, 3. Panacea Biotech 4. Nicholas Piramal

6. Venkateshwara Hatcheries, 7. Wockhardt, 8. GlaxoSmithKline 13.Krebs biochemical,

18. Syngene Internationals

This was also supported by the senior managers of panacea through discussions.

Along with the total manpower position for these two years i.e. 2002-03 and 2003-04, category wise unfilled positions were also enquired into for all companies.

A list of categories or job covered for projection is as follows

1. Scientist R and D
2. Engineers (all departments)
3. Technicians (Skilled)
4. Regulatory/ Clinical affairs
5. Production (Skilled + Unskilled)
6. Marketing
7. Finance

8. Human Resources

9. Licensing / Administration

10. Project Management

11. Purchase

The reasons for selection of these 11 categories are stated below. It was seen in chapter III, biotech operations and organization that the task requirement and stage wise changes in workforce take place in the natural course of development of biotech business. In chapter IV the typical job positions available in a biotech organization were also described in detail. The knowledge and skill base for typical positions was also described along with job descriptions and job specifications. After that the organizational design on the basis of task description was also discussed. In all companies the employees are described category wise, for the sake of identification of employee's position in an organization. For example a Manager could be a production Manager, finance manager or HR manager. The companies also make and keep record of unfilled position categorywise.

The departmentalization decides the category label of an employee for purpose of planning. With this information and the experience during primary discussions for case studies and pilot survey with managements of biotech companies, it was decided that, these categories are sufficient and essential for the purpose of projection. Two years viz. **2002-2003 and 2003-2004** were considered for purpose of collecting the necessary data, as was stated above. Table 6.2 represents Change in Manpower in two years for each company.

Table 6.3 tabulates the unfilled position percentages for each company for all categories.

The percentages have been calculated and tabulated for the purpose of analysis which can make estimation of demand for forecasting possible. Percentages also bring in the element of objectivity in the analysis.

Table 6.2 Change in Manpower in two years for each company

Name of the company		2002-2003	2003-2004	% Increase
Biocon	1	600	892	**48.67**
Serum Institute	2	1715	1930	**12.54**
Panacea Biotech	3	1400	2000	**42.86**
Nicholas Piramal	4	2000	3000	**50.00**
Novo Nordisk	5	180	274	**52.22**
Venkateshwara Hatcheries	6	110	135	**22.73**
Wockhardt	7	2300	3500	**52.17**
GlaxoSmithKline	8	4800	5700	**18.75**
Bharat Serums and	9	N.A.	N.A.	**N.A.**
Eli Lilli & Co.	10	520	537	**3.27**
Novozyme	11	2100	3900	**85.71**
Quintiles Spectral	12	N.A.	N.A.	**N.A.**
Krebs biochemical	13	290	625	**115.52**
Indian Immunological	14	210	408	**94.29**
Zydus Cadila	15	N.A.	N.A.	**N.A.**
Mahyco Monsanto	16	N.A.	N.A.	**N.A.**
Shantha Biotechnics	17	476	600	**26.05**
Syngene International	18	172	265	**54.07**
biological E	19	262	378	**44.27**
Span diagnostics	20	475	522	**9.89**
		17610	**24666**	**40.07**

It emanates from these data that

1) In the case of each company, the number of workforce employed is on the increase. This was also observed during the review of biotech businesses on global level and from data of HR trend, yearwise.

2) Demand position for each category is as under in table 6.3

Table 6.3 Unfilled Position Percentages for Each Category

Code no. of Company	Scientists R & D	Engineers (All Departments)	Technicians(skilled)	Regulatory/Clinical Affairs	Production (skilled unskilled)	Marketing	Finance	Human Resources	Licensing /Administration	Project Management	Purchase
1	33.33	8.33	16.67	0.00	33.33	0.00	8.33	0.00	0.00	0.00	0.00
2	20.83	8.33	12.50	8.33	20.83	8.33	4.17	0.00	8.33	4.17	4.17
3	22.22	11.11	5.56	5.56	44.44	11.11	5.56	11.11	11.11	5.56	5.56
4	13.04	4.35	13.04	8.70	17.39	13.04	4.35	8.70	4.35	8.70	4.35
5	16.67	16.67	11.11	5.56	16.67	11.11	5.56	0.00	5.56	5.56	5.56
6	10.53	15.79	10.53	10.53	15.79	10.53	5.26	0.00	5.26	10.53	5.26
7	10.00	15.00	10.00	10.00	15.00	5.00	10.00	5.00	10.00	5.00	5.00
8	8.33	11.11	8.33	11.11	13.89	8.33	11.11	8.33	8.33	5.56	5.56
10	12.50	12.50	6.25	12.50	6.25	12.50	18.75	12.50	0.00	6.25	0.00
11	21.43	7.14	0.00	21.43	0.00	7.14	14.29	7.14	7.14	7.14	7.14
13	20.00	6.67	6.67	13.33	6.67	6.67	13.33	6.67	6.67	6.67	6.67
14	0.00	0.00	18.18	9.09	18.18	9.09	9.09	9.09	9.09	9.09	9.09
17	15.38	7.69	7.69	7.69	15.38	7.69	15.38	7.69	0.00	7.69	7.69
18	0.00	0.00	18.18	9.09	18.18	9.09	9.09	9.09	9.09	9.09	9.09
19	16.67	11.11	5.56	11.11	11.11	0.00	11.11	11.11	0.00	11.11	11.11
20	15.38	7.69	7.69	7.69	15.38	7.69	15.38	7.69	0.00	7.69	7.69

It can be seen from the data in table 6.3 that

1. For all companies there are unfilled positions in one category or other.

2. The maximum unfilled positions are for following categories.

   a) Production, b) Scientist R and D

3. As responded explicitly by management of all companies that the reason behind unfilled position is lack of qualified candidates, i.e. non-availability of them.

4. By and large the companies do not think that "compensation expected by qualified candidates is too high" is the reason for the positions remaining unfilled.

The unfilled positions for all categories for all companies were summed up and percentages of category to totals of all unfilled positions are displayed in table 6.4 for the purpose of analysis

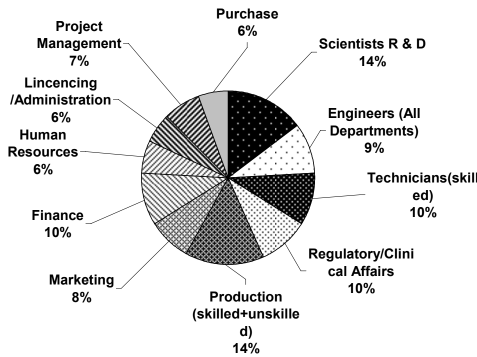
Table 6.4 Total % of unfilled positions, for each category

Position /Category	**Percentage**
Scientists R and D	14%
Engineers (all departments)	9%
Technicians (skilled)	10%
Regulatory /clinical affairs	10%
Production (skilled + Unskilled)	14%
Marketing	8%
Finance	10%
Human Resources	6%
Licensing / Administration	6%
Project Management	7%
Purchase	6%
Total	100%

The total of category wise percentages shows the category wise demand of human resource for the biotechnology sector in a representative manner.

A pie chart of category wise unfilled positions percentage for all the companies can be useful for estimating category wise demand of human resource in biotechnology.

Fig. 6.4 Estimation of HR Demand- Category wise Percentages



It should be noted that this is one of the methods in the absence of any other method being followed. Planning activity is generic in nature and forecasting the demand in tune with vision and mission, as per the operational need is satisfied by the normal planning in the beginning.

As an example for individual companywide category wise demand percentages, we can draw pie chart for a particular company. Following conclusions can be drawn from the forecasting method for estimating demand in terms of category wise percentages. All categories of employees for biotechnology are in demand in various percentages.

1. The maximum percentage is that for two categories:

   R and D (14%) and Production (14%)

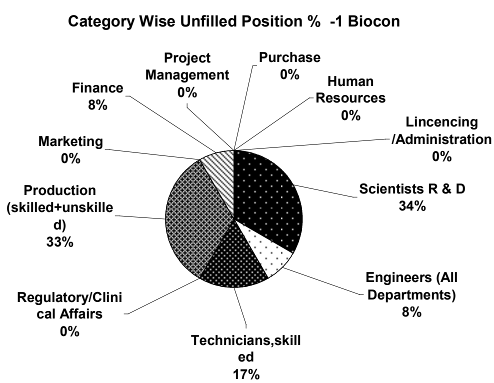
2. Regulatory/clinical, Technicians, Finance, these three are second in line (10%)

3. Then Engineers 9%, Project Management 7% and Purchase, Licensing/Administration and Human Resources are 6 % each.

It is understood at this point that the situations of demand of manpower are changing rapidly as per changes in strategy, retirement of old employees, and employee turnover for whatever reasons. So the above estimation is a trend estimated on the basis of data for the years 2002-03 and 2003-04 for the selected biotech companies. So the numerical conclusions may not be profound, however, the "general trend" inferences could be far-reaching and valid.

Forecasting of demand trend for a particular company is possible with this kind of "forecasting % demand for each category" method.

Fig. 6.5 Unfilled Position %- Biocon for each category



The data was collected for selected companies; and this estimation is presented here for Biocon, as an example.

This graph can be one of the tools for a company to estimate the comparative manpower demands category wise, when absolute figures are not required for the purpose under consideration, like the present study.

6.2 Supply of Human Resources

It is in a way easier for companies to work out details using their own database for forecasting the demand of human resources for the purpose of human resource planning. When they are doing the work for their own organization they know everything necessary for calculation and estimation of category wise HR demand. The supply of the necessary human resource has to be obtained as fast and as efficiently as possible for maintaining the operations of the organization at desired level.

The companies need to envision human resources as flowing into, through and out of organization. Like any other resource, human resources are subject to subtle erosion. In biotech sector employees leave organizations for variety of reasons. Whatever may the reason be, the gap must be filled in by replacing the number and category which has left the company.

What the company executive under the guidance of senior management normally practices for filling in the gap in terms of unfilled positions or estimated demand etc. is to look towards the sources of supply. The methods of finding the supply source depend on the level at which the employees are required. An important aspect of HR planning is to decide how many people of what qualification and experience are required within what time frame? Some of the sources utilized by the biotech companies are discussed below.

For entry level positions, educational institutions are the best source. These are utilized by the companies by way of knowing the subjects and strengths of the student's against their own requirement. Campus interviews, summer placements, internships etc are some of the ways for locating, testing and estimating the capacity of such sources for recruitment of candidates at entry level positions.

For senior level technical and managerial positions, placement agencies and consultants is a method of choice. This is done because sometimes this part of the personnel function is outsourced. Another reason for this is keeping confidentiality and avoiding the inflow of a large number of applications. The population explosion and availability of education produces a large number of graduated, post graduated and doctorate candidates throughout the nation every year. However, this information is not enough. Biotechnology needs people of particular qualification and experience to satisfy the demand, which has been estimated.

One of the main objectives of the present study is to identify the skill sets required for biotechnology operations, the job descriptions and job specifications for typical biotech operations. This information was not available to company executives in a systematic and comprehensive manner. At present time the need of the biotech industries in terms of skill sets and necessary educational background is not exactly catered to by the existing educational and training institutions as their curricula need to be modified addressing the needs of the biotechnology industry. This is a hurdle in the way of estimating the supply of human resource which is "biotechnology-job ready" as per the industry standard.

All the same, the task of writing job specifications while publishing advertisements either through a manpower consultant or directly through an advertising agency is done as and when required and no reference manual for this purpose is available. Advertising the category wise demand in news papers or journals in the geographical location from where the manpower is to be attracted, is one more source of forecasting the supply of required manpower. This is all known to the management and executives who handle the HR function, however not all the people can follow these ideal practices all the time and the discussion about the

reasons for the same is useful for throwing light on this issue in the perspective of present study.

6.2.1 External Sources of Recruitment

Availability of education and training facilities, standards of the educational institutes are important factors which play a major role in the availability of right type of skills or human capital for biotech business. While making note of educational requirements for carrying out tasks in biotechnology industry, it was understood that educational requirements for biotechnology operations are multidisciplinary and can be classified as a super specialty in itself. The analysis of the educational and training facilities from the point of view companies reflects that the standard of education in general is not what is required to make the candidates' job ready. For reviewing these facilities at macro level, the list of such educational institutes would provide a basis. For example, there are seven autonomous institutions initiated under the aegis of the Department of Biotechnology, and from their addresses there spread all over the country can be understood. They are listed below.

DBT Autonomous Institutes

1. Director, Centre for DNA Finger Printing and Diagnostics, ECIL Road, Nacharam, Hyderabad–500 067, Ph: 91-40-27151344, Fax: 91-40-27155610, Website: http://www.cdfd.org.in
2. Director, National Brain Research Centre, SCO-5, 6 & 7, Sector – 15, Part-II, Gurgaon-120001, Fax: 91-124-6220237, email: info@nbrc.ac.in, Website: http://www.nbrc.ac.in
2. Director, National Centre for Plant and Genome Research Centre, JNU Campus, ICGEB Hostel, Room No. 11 & 12, P.B. NO. 10531, New Delhi – 110 006, Ph:- 91-11-26704560,

26187224, Fax: 91-11-2616 7394, 26169962, Email: webmaster@mail.jnu.ac.in,

Website: www.dbtindia.nic.in/institutions/ncpgr.html

4. Director, National Institute of Immunology, Aruna Asaf Ali Marg, New Delhi-110 067, Fax: 91-11-610 9433,

Website: http://www.nii.res.in

5. Director, National Centre for Cell Sciences, NCCS Complex, Ganeshkhind, Pune 411 007, Fax: 91-20-5692259,

Email: infoncss@giaspn01.vsnl.net.in,

Website: http://www.nccs.res.in

6. Director, Institute of Bio resource & Sustainable Development, C/o MASTEC, Central Jail Road, Imphal, Manipur,

Fax: 91-385-406041/230 037.

7. Director, Institute of Life Science, Nalco Square, Bhubaneswar, Orissa, Ph: - 91-674-2300137, 2301460, 2301476, 2300129,

Fax: 91-674-2300728, Email: scsabat@yahoo.com

Website: http://www.ilsc.org

Besides these seven institutions there are other 88 institutions /universities in India which offer biotechnology education and the list is available with the DBT, i.e. The Department of Biotechnology, Government of India.

According to the National biotechnology policy[1] draft **"Reliable Estimates of Human Resource Availability for the next 10 years are Required."**

The reasons for the same are noted as under:

- Expert consensus indicates that there is an adequate enrollment currently at the post-graduate and under-graduate levels, however the quality is inconsistent.
- Areas such as intellectual property rights, regulatory issues and industrial training have received inadequate attention.
- There is a consensus that there is an urgent need to augment the number of Ph.D. programs in the Life Sciences and biotechnology.
- A strong pool of academic leaders is key to sustained innovation.

The above statements about status of supply position for Human Resource for biotechnology make the point of forecasting supply and efforts for forecasting the supply sources very clear. At policy level there are strategic requirements written down. (In the context of the present study, the researcher wants to submit that the work undertaken by him may provide a niche, for the policy makers.) The strategic actions suggested for achievement of the proposed objectives by the policy are,

(i) National Task Force on Education & Training

- A National Task Force will be created to formulate model undergraduate and postgraduate curricula in Life Sciences keeping in view, future needs. The said curricula must address the underlying need for multi-disciplinary and inter-disciplinary learning and the appropriate stage for biotechnology training.
- There would be need assessment in 2005 for the next five years and close monitoring during the period for interim changes.
- **A 10-year Perspective Plan for Human Resource will be Prepared Every Five Years.**

(iii) Curriculum Development

- Course curricula will be reviewed and improved in consultation with industry and research establishments and standard e-learning modules will be developed for specific skill areas such as IPR, regulations, and bio-enterprise.
- Hands on exposure to M. Sc. biotechnology students will be enhanced through an extended industry internship as well as through short-term placements at CSIR and other appropriate National Institutes.
- **Dual degree programs in biotechnology that include regulatory matters, IPR and bio-enterprise management will be encouraged** and supported by the Department of Biotechnology.
- Emphasis will be given on training of high quality technicians and technologists in skills required by the industry by establishing Regional training centers at diploma, graduate and postgraduate levels.

(iv) Quality Improvement

- An accreditation mechanism will be put in place for ensuring minimum **standard of education and training** at the post graduate and undergraduate levels. Base requirements for teaching and laboratory infrastructure will be specified and enforced.
- Teachers training programs will be taken up by creating regional teachers training centers

(v) Strengthening of Teaching and R&D in Life Sciences and Biotechnology in the University System

- Strengthening R&D in Life sciences and biotechnology in the university system will be accorded high priority. This is considered

important for improving the quality of education and providing exposure to new technologies for students at various levels. Specific mechanisms to achieve the goal will include

- Creation of inter-disciplinary centers of excellence with world class infrastructure in key areas
- Program support to encourage inter-departmental networking
- Visiting professorship and creation of industry sponsored chairs in partnership with the Department of Biotechnology.

(vi) Attracting Talent to Life Science and Biotechnology

- Bright students will be attracted to take up careers in biology and biotechnology through special scholarships. Summer assignments at Academic and Industry research laboratories will be introduced at the school level to create interest in the fields of biotechnology and biology
- Women scientists will be encouraged to take up careers in biotechnology. Service conditions will be liberalized for women to be able to return to research/academics after maternity breaks.

(vii) Creating Science & Technology Leaders for the Industry

- The number of Ph.D. fellowships offered by the Department of Biotechnology will be increased to 200 per annum
- Public-private partnerships will be encouraged in Ph.D. programs through creation of the 'Bio-edu-Grid'- a network of universities and industries facilitating pooling of resources.
- Masters degree level professionals in industry will be encouraged to undertake Ph.D. programs while retaining their jobs through industry-university tie-ups.

(viii) Arresting and Reversing Brain Drain

- As mentioned earlier, the number of postdoctoral fellowships offered by the Department of Biotechnology will be increased to 200 per annum in order to attract talent.
- Outstanding young investigator grants in biotechnology will be introduced. This will provide a package including salary support, research grant, equipment and opportunities to attend national and international conferences. The salary support under the scheme will be at par with that of entry-level faculty positions.
- Information on availability of positions in education/research establishments and industries will be provided on a website to facilitate employment of scientists with specific skills at appropriate positions.
- A database of scientists working in different areas of biotechnology within and outside the country will be created to utilize the expertise appropriately.

(ix) Enabling Working Conditions for Scientists to undertake Industry Oriented Research

- *Lateral mobility of scientific personnel:* Scientists working at universities and research institutions may be allowed to work in industries for commercialization of their research efforts. This could be in the form of a consultancy with industry or by a sabbatical for three years during the working life of scientists
- *Dual/adjunct faculty positions:* Researchers working in university/research institutions may be allowed to hold positions in the industry and vice-versa
- *Joint salary support:* Faculty employed in academic institutions may be allowed to hold positions for a period of time in which their salary is contributed both by the industry and the academic

institution on a mutually agreed basis. (Such an arrangement will work well only if the teaching requirements of the academic institutions are made obligatory).

- *Rapid travel grants:* Rapid travel grants scheme for approval within two weeks for young scientists to interact with mentors and industry collaborators would be initiated.
- *Institute Innovation grants* through the Department of Biotechnology to fund academic researchers to develop their concepts into patentable and more importantly licensable technologies. Such grants may be utilized for the purpose of providing additional infrastructure and manpower, patenting costs as well as costs related to proof of concept studies.

These steps will ensure that the large available resources of human talent in biotechnology are supported and this will guarantee the progress of the biotech sector.

These proposals in the policy have taken care of the supply source forecasting and meeting the demand of the biotechnology sector in India. This should be considered as relief for mangers in the biotech sector looking after HRM function. Now they can use all the planning tools and processes they find suitable, with the active participation of senior managers. Then they can interact with the DBT and policy makers so as to help implementation of policy.

As it can be envisaged, this is a slow process and would take time. Till such time, that the proposals in the policy become a reality, it is a testing period for biotech sector. Taking hint from this people in HRM for biotechnology can become proactive.

An exhibit - 3 "Biotechnology HR Some Observations" is presented on the next page.

6.2.2 Internal Sources of Supply:

The discussion about forecasting sources of supply includes both external and internal sources. The external sources have been discussed above. The internal source is the pool of workforce which has already been recruited by the company for the purpose of carrying out the mission of the company in terms of providing products or services it had decided to provide to the society at large. This pool of experienced workforce is the source in the sense that people who have been provided assistance for career growth, to upgrade their knowledge and skill level above the level at which they possessed at the time of entry in the company. To that extent it can be termed as a potential source of supply. This supply can be nurtured, which calls for a planned activity of career development and mentoring. The employees developed in such manner can be considered for promotion, appointment for new project as useful resource, can become a mentor for new entrants and so on.

This source of supply is the one over which the company can have good degree of control, provided necessary planning and implementation of the same has been undertaken. This issue also involves training and development, and is considered in details while discussing those issues in the next chapter.

6.3 Factors affecting HR Planning

The general constraints associated with forecasting of demand and supply of human resources for biotech industries, which forms the basis of human resource planning activity, can be stated as follows.

A. Factors with LONG RANGE effect:

6.3.1 Growth of Organization: The information and data in the table 6.5 emanates that, the major hurdle in planning process and procedure was Growth of the organization. This is because 80% of the

Exhibit -3 Biotechnology HR in India: Some Observations

These observations are based on the basis of detailed discussions held with HR managers of biotech companies and biotechnologists.

Resource crunch: Lack of educational facilities of appropriate standards: Creating laboratories equipped with state of the art technology instruments involves innovative scientists and budgetary provision. Further, to run and maintain the laboratory for research for educational purpose also need funds, grant, faculty for carrying out research and for transferring the research skills of industry standards to students. This explains that resource crunch is a major problem.

Academic Taboos: is biotechnology an applied science? is it engineering and technology? Is the person working a scientist, engineer or a laboratory technician? Who is supposed to handle the equipment, when it comes to standards like Good Laboratory Practices, SIP and CIP? At what level of education these techniques be introduced? Under graduate, Post graduate modules or Para-studies.

Scale of Operations: whether the scale of operations can be small or does it have to be big? This point springs from the nature of technology and its applications in terms of individualized medicines, individualized vaccines and pest control etc. for agriculture. Skepticism about the economy of scale has a basis of application on individual level. This is discussed here only to the extent it involves the magnitude of human resources in tune with the scale of operation.

Special Focused Efforts: The biotech sector is emerging and is not established as the information technology sector. The infrastructure necessary for training and development of human resources for biotech sector is not simple and is very technical. This is so because computer education has began at school level, and there is a drive to reduce the digital divide by attempts to eradicate computer illiteracy. No such drive for biotechnology awareness at any level is in existence. Another issue is, careers in other technologies are established and good motivation is provided by national and international companies by providing infrastructure and facilities suitable for the development of the HR and technology. Some focused efforts for biotechnology sector development are necessary.

respondents have agreed that for both the years (2002-03 and 03-04) that there was expansion being implemented.

Table 6.5 Factors, Constraints Associated with HRP

Sr. No.	Factors Responsible on a scale of five grades	2002-2003					2003-2004				
	1=20%, 2=40% 3=60% 4=80%, 5=100%	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
A	**LONG RANGE Effect**										
1	**Growth of Organization**				√					√	
2	**Budgetary Constraints**	√					√				
3	**Lack of Appropriate Training and Education**			√					√		
4	**Matter of priority**	√					√				
B	**SHORT RANGE Effect**										
1	**Change in Technology**				√					√	
2	**Production Policy**			√					√		
3	**Promotion Policy**			√					√		
4	**Lack of Succession or Replacement Planning**				√					√	
5	**Lack of data such as Skill Inventory**				√					√	
6	**Any other**										

As a result, the monitoring of infrastructure and other production facility became more important and HR planning was on tentative level, on the need basis. Moreover, forecasting of manpower with specification is not yet a routine matter and any other priority can side track the HRP function.

6.3.2 Budgetary Constraints: this was another hurdle as communicated by 20% of the respondents. They also added that it was budgetary hurdle, for these two years, because of which they could not propose any extra activity like systematic HRP.

6.3.3 Lack of Appropriate Training and Education Facilities / Institutions: Sixty percent of the respondent's opined that lack of appropriate training and educational facilities and nonavailability of database of their output (number of students passing out) with qualification standards were a hindrance in the process of HR planning in terms of forecasting supply. As a result the long range planning cannot be undertaken because the factors like educational and training facilities required to plan ahead are lacking and also can not cater to all the existing needs of Indian biotech companies.

6.3.4 Matter of Priority

In factors affecting long range planning 20% respondents confided that HR planning activity is not normally considered to be of primary importance. They expressed a need for proper method for working out all the HR planning activities, including those of training and development and the facility should cover all the parameters of HR planning.

B. Factors with SHORT RANGE effect:

6.3.5 Change in Technology was a factor which actually calls for more planning by remaining alert about the changes in the offing and preparing the management of the organization with the necessary information and database for HR planning. Though the effect is short term the anxiety it can create is greater, because the change in technology implies many internal and external changes, and need for adaptation, and adoption etc. 80% of the respondents reported this as a factor which affects HR planning.

6.3.6 Production Policy has many connotations and the changes in the same may be necessary because of market need or raw material or other process material supply conditions, power and climate, natural or man-made calamities etc. The change in production policy is a factor affecting HR planning was the opinion of 60% of the respondents.

6.3.7 Promotion Policy of a company is a crucial factor which affects the planning of HR and 60% of the respondents have indicated that Promotion policy of a company affects the employees' right from the stage of recruitment. If the promotions are going to be through internal manpower as a matter of policy, with exceptions clearly stated (like emergencies due to new projects involving new technologies, etc), the training and development has to be planned in tune with the policy and career prospects for employees become bright and in a way assured.

6.3.8 Lack of Succession or Replacement Planning:

The planning process or effect of good planning goes haywire if there is no succession or replacement planning. Replacement of a sudden change (job hopping for better prospects, personal reasons etc) may become a problem and if such a position happens to be a key position in the whole organizational chain then it really affect the performance adversely. 80% of the respondents agree with this that lack of succession or replacement planning adversely affects planning and its expected outcome.

6.3.9 Lack of Data such as Skill Inventory: Basic need of HR planning for staffing, recruitment, promotion etc. is skill inventory. These skills include technical as well as managerial, and soft skills necessary for all, so as to effectively function in an organization. In the absence of such an inventory, because biotechnology is relatively new, even the educational and training institutes cannot properly plan their syllabi for various courses. In companies, skill inventories are more valuable, and job

descriptions and specifications cannot be prepared satisfactorily in the absence of the same. 80% of the respondents are of the opinion that skill inventories are must and lack of them is a great negative factor affecting the HR planning process.

6.3.10 Demand Supply Situations and Actions -

Because of the internal and external factors which affect demand and supply of manpower there may arise various situations. It is seen that the following situations have taken place.

High Supply of HR and High Demand for the same (100%)

Computer Skills for administration, Presentation etc.

Action Expected

a) Change in entry level skill standard and proficiency level.

b) Computerized automation of other business processes wherever necessary, is possible.

2. Low Supply of HR and High Demand (for 80% respondents) a) Scientist R and D.

Action Expected

a) Initiatives by companies for becoming accredited research centers, providing career path for scientists.

b) Patent registration and protection of IPR

Low Supply of HR and High Demand (80 % respondents)

b) Production technologists for commercialization

c) IPR, regulatory issues. d) OSHA, GMP, GLP etc.

Action Expected

b) Industry institution cooperation for necessary education and training, with certification.

3 High supply and Low demand 80% of respondents

Technical and non technical trainees

Action Expected

a) Evolution of special professional training facilities by state and other institutions for making candidates industry ready.

b) Administration of Aptitude and General intelligence test for New entrants

6.4 Conclusion

Demand and supply of human resources are important parameters for consideration of human resource planning and development. Forecasting the demand is a management function, preferably handled strategically. For forecasting the demand the vision, mission and objectives of a company become important. These factors indicate the type of people required, when they will be required and from where they can be obtained at optimized cost. The supply sources are both, external and internal and HR from both the sources may have training needs. The factors affecting HRP in long range and short range are identified through enquiry with selected companies. The various demand supply situations have also been described with expected actions. This forms the basis of HR planning and development processes and these processes are presented in the next chapter VII HR Planning and Development Processes – an analysis using factors.

ENDNOTES

[1] http://dbtindia.nic.in/biotechstrategy/Biotech%20strategy.doc

Chapter VII

HR Planning and Development Processes
–An Analysis using Factors

7.0 Introduction

As observed through discussions in earlier chapters that HR planning links 'People Management' with business objectives, operational details, tasks and their organization through departments' formation and overall strategy of the company. It can also be observed that this link facilitates writing job descriptions and job specifications. This in turn provides a direction for job positions available in a business. The skill sets along with job descriptions can be used for human resource planning and development, keeping in mind the objectives of the organization. The HR plan so developed by an organization serves as a base for many purposes including identifying HR requirements, reducing the time and cost of future staffing, signaling potential workload or workforce adjustment situations, predicting shortfall in the workforce and market availability status, highlighting projected retirements and resignations and developing retention and succession policies.

Although development of HR plan has been the task left to HR departments, it is observed through case studies and questionnaire survey that in case of biotech organizations the same is formed a part of strategic management in biotech businesses, more so for the part of the HRM related to retention. The HR planning and processes were reviewed for selected biotechnology companies and the outcome of the process is presented in this chapter.

7.1 HR Planning and Development Process

The HR planning and development process was reviewed against the background of following framework of enquiry..

1. What are the strategic objectives of the organization?
2. What are the organizations current or existing workforce needs?
3. Are existing employees sufficient? Are there any unfilled positions?
4. What is the organizations future supply of employees? What is future demand of employees?
5. Which types of competencies are required?
6. How many people will be needed with what skills and what competencies?
7. Are there employees with appropriate development who could undertake the tasks for efficient performance?
8. How are the development needs addressed? Are there any difficulties faced by the management while addressing the same?

Most of the above questions are addressed by several aspects of HR planning and development processes as practiced by organizations in their effort to satisfy the objectives of the organization. The aspects making the process successful or the factors making the process successful were identified for and during the enquiry are Recruitment, Retention, OD-Change Management & Training and Development, Management Development, etc. The analysis of the HR planning and development processes using these factors is presented for the selected biotech companies, in the following lines.

7.1.1 Recruitment:

Forecasting of demand and locating sources of supply is the background preparation necessary for initiating the recruitment process. Recruitment process is the first step in filling in the positions available in the company so that all the tasks are attended to and completed in time as

per the quality standards assured. For initiating the recruitment process, identification of job skill and competency is one of the primary needs.

The skill set requirement has been listed after collecting the responses from selected companies and by grouping them sector wise. First the technical skills and competencies are listed in alphabetical order.

Biotechnology Skill Sets and Competencies – Sector wise

Bio-Pharma or Healthcare:

1. Antibody Production, 2.Basic Animal Care, 3.Bio-Safety Guidelines, 4.Cell Culture, 5.Column Chromatography, 6.Database, 7.DNA Isolation, 8.DNA Sequencing, 9.DNA Synthesis, 10.ELISA,

11. Gel Electrophoresis, 12.Good Clinical Practices (GCP),13. Good Laboratory Practices (GLP), 14.Good Manufacturing Practices,

15. Groupware/IT, 16.High Pressure Liquid Chromatography (HPLC),

17. Hybridoma Techniques 18. Immuno-Precipitation, 19. In Vitro Mutagenesis, 20.In Vitro Transcription, 21. In Vitro Translation, 22.Instrument Validation, 23.IPR Related, 24.Live Animal Handling,25. Mutagenecity Testing, 26.Polymerase Chain Reaction (PCR), 27.Peptide Synthesis, 28.Protein Purification, 29. QA/QC Procedures, 30.Recombinant DNA Technologies, 31.RNA Isolation, 32.Southern Blotting, 33.Sterile Technique, 34.Bioinformatics, 35.Image Analysis, 36.Imaging, 37.Spreadsheet, 38. Word Processing, 39.Presentation, 40.Graphics

Industrial Biotech:

1.Bio-Safety Guidelines, 2.Cell Tissue Culture, 3.Column Chromatography, 4.Database, 5.DNA Isolation, 6.DNA Sequencing, 7.Gel Electrophoresis, 8. HPLC. 9.Instrument Validation, 10.IPR Related,

11. Polymerase Chain Reaction (PCR), 12.Peptide Synthesis, 13.Protein Purification, 14.QA/QC Procedures, 15.Recombinant DNA Technologies

16. Spreadsheet, 17.Sterile Technique, 18.Word processing.

Agricultural Biotech

1. DNA Isolation, 2.DNA Sequencing, 3. DNA Synthesis, 4.Good Laboratory Practices (GLP), 5.IPR related, 6.Hardening of Plants,

7. Polymerase Chain Reaction (PCR), 8. QA/QC Procedures, 9.Recombinant DNA Technologies, 9. Sterile Technique, 10. Tissue Culture, 11.Spreadsheet, 12.Word Processing, 13.Presentation, 14.Graphics

The difference in application of skills in different sectors was explained by the final product or service which is being provided by a particular company. Through discussions with biotechnologists in industries, it was also noted that the sector wise skill requirement is seen the way it is presented above, because of the extent of biotechnology which is being used by companies being studied. When the skills and competencies' list applicable in Bio-Pharma or healthcare biotech was validated with those companies and other academic biotechnologists, engaged in basic and applied research, they were of the opinion that the use of biotechnology in Indian companies is comparable to the global use, in terms of different techniques available as on today.(2004-2005). It is interesting to note here that plant tissue culture and related techniques could be useful in bio Pharma as well as industrial biotechnology, as it is the use of the final product or service is the basis for sectorial classification of biotechnology, in the context of the present study. This is the same system of sectorial classification which has been followed throughout all descriptions.

Managerial - Specific Function Skills: manpower is recruited for technical functions, and managerial functions and combination of both. We have discussed categorywise manpower requirement and the list of specific function skills is given below. The orientation training need for entry level candidates is tabulated as aggregate percentage requirement for each specific function listed in Table 7.1

Table 7.1 Entry Level Training Need % for Specific Function Skill

Specific Function Skill	**Training Need at Entry Level**			
A=Always, O=Often S=Sometimes, R=Rarely	**A**	**O**	**S**	**R**
Marketing	21%	58%	21%	0%
Human Resources Planning	11%	63%	26%	0%
Human Resources Training and Development	16%	73%	11%	0%
Finance, Business Economics	21%	58%	21%	0%
Customer relationship	21%	63%	16%	0%
Bio-safety	32%	68%	0%	0%
Regulatory affairs	32%	57%	11%	0%
Licensing / Administration	26%	58%	16%	0%
Production	39%	52%	9%	0%
Third Party Certification e.g. ISO	16%	52%	32%	0%
Research and Development	21%	58%	21%	0%
Ethics	26%	58%	16%	0%

It is seen from the data that while recruiting people for specific function, biotechnology companies have expressed a need that for all the functions listed, viz. Marketing, Human Resource Planning, Human Resource Development, Finance, Business Economics, Customer relationship, Bio-safety, Regulatory affairs, Licensing/Administration, Production, Third Party Certification e.g. ISO and Research and Development and Ethics, the entry level candidates need to be given orientation training.

From the point of view of optimization of the period of training, after recruitment, it is necessary to screen the candidates for competencies during recruitment. This was the opinion of about 80% of the HR managers. This reflects on the quality and standard of management education provided by educational institutes in India. There is a gap between the curriculums and what biotechnology industries need. The recruitment method and process as followed in Indian biotech companies is as follows.

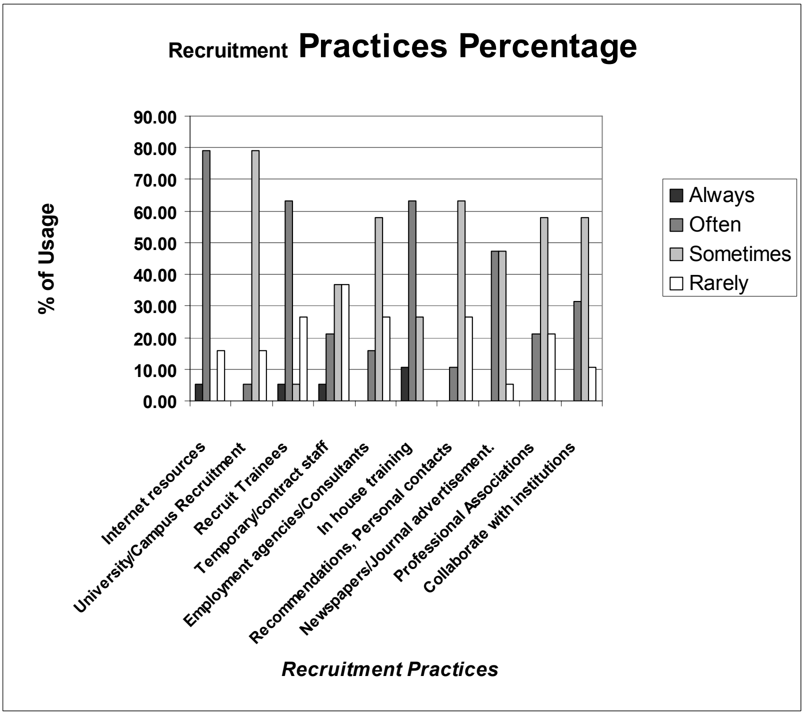
Recruitment Method and Process:

Methods: For filling in the unfilled positions in a company, recruitment is done. Various practices are shown in fig. 7.1

The job description and specifications which have been described in chapter IV are typical for biotech, and each company used various methods and modes for implementation of the recruitment process.

It can be observed from the graph in fig 7.1 recruitment practices followed by companies that various methods used by companies can be listed with comments which will help us analyze the situation. The various ways in which companies recruit manpower are described.

Fig. 7.1 Recruitment Practices



Internet Resources: Web sites are the medium for advertising along with the print medium. Internet access is necessary for viewing the ads on websites of companies. Companies use internet resources for advertising and getting response to the same. This method saves time and with automation, sorting out resumes becomes easier and faster. The companies either advertise on their own web site, on web site of a recruitment agency, and in addition in the print media. From the above graph it is seen that internet resources are used by all the companies. 80% respondents say often, and remaining fall in the category always, sometimes or rarely.

University/Campus Recruitment: This is a method which is often followed by about 5% of companies. It is sometimes followed by about 80% and about 15 % rarely follow it. This method involves establishing a

liaison with institutions. And when there is a need of fresh graduates and post graduates, this method is followed. There are advantages in this method that one can evaluate the standard of education and training of the institute, suggest some specific need of company or sector and then hope for better preparedness of the candidates for the prospective jobs. The disadvantage is that the in the vast market, the source as an institution has limitations of quantity and quality.

Recruit Trainees: Trainees are often recruited by more than 60% of companies. The choice of this method is for obvious reasons that one catches them young and trains them to suit the needs of the organization. This is followed as a policy by 5% of companies, who have responded as "Always" to this method.

The data collected for recruitment of trainees, from the companies when analyzed, showed that the range of technical trainees is from 85% to 95%. The percentage of trainees from non-technical areas like finance marketing HR etc is from 05% to 15%. For emerging nature of the biotech businesses, this percentage is very much in its natural course since the technical requirements supersede the non technical functions.

However, non-technical functions like marketing, finance and HR are covered by only 05% to 15%. The above analysis indicates that, **"The proportion of non-technical trainees in comparison with technical trainees is marginal"**

Temporary/Contract Staff: As a policy, this method is followed by about 5% respondents and about 35% companies follow this sometimes. There are various reasons for retaining temporary or contract staff. It could be that, the temporary nature of work or contractual agreements for security and transportation kind of work.

Employment Agencies/Consultants: This method is often used by about 60% respondents. This becomes useful as a time and effort saver, if

one has a reliable agency. This is used occasionally because it may be more expensive than handling the recruitment in-house.

In House Training: As a policy matter 10% companies follow this and 60% companies often do it. This is done on the need basis and decided by the HR managers for that situation at that point of time, when requirement emerges. .

Recommendations, Personal Contacts: About 10% respondents have reported that they use this method often and other 60 % sometimes. The comment is that for reliable recruitment sometimes this method is more effective.

Newspapers/Journal Advertisement, Professional Associations

Collaborate with Institutions are some of the other methods and the explanation of the graph is on the same line, and therefore has not been elaborated. For the alternative, "**any other (please specify)" _ question was asked.** No other method was reported by any of the companies as a method of recruitment.

As described above, there are several methods which are being followed by the companies for recruitment. The process presents a scenario which is summarized below, as shared by the HR managers of different companies.

1. There is no special source of recruitment although the environment and technology of biotech businesses is different from engineering or chemical and such other established businesses.

2. Therefore it can be said that "The sources of recruitment and their usage, for biotech and non-biotech businesses are similar" using the description and the graph presented above.

There are several stages through which this process has to pass. The first is of course planning of the human resource. Then using one of the

methods listed above, it is made public that company needs manpower. In that communication the job description and specification is not given to the extent it is required for planning of HR. The description of the category of the position like management trainees, senior manager, and regional manager etc. function wise is given. This means for marketing, production, finance, administration, HR, training and development etc. When senior posts are advertised, then regional marketing manager, vice president marketing, sales manager etc are appropriate descriptions. As an example the excerpt of an advertisement on the web site of one company Panacea Biotech is given below

Panacea Biotech *is a leading research based Health Management Company, with an annual turnover of approx. Rs. 285 Crores. Panacea Biotech manufactures and markets vaccines, bio- pharmaceutical and pharmaceutical (Rx and OTC) based products of international quality. All Panacea Biotech plants are accredited by international agencies and they follow current Good Manufacturing Practices, as per WHO guidelines. We require young, aggressive, dynamic, high performing Personnel in tune with our plans.*

Designation : Validation Engineer

Job Description: Responsible for successful completion of validation and calibration leading to successful installation of equipment/ instruments and commissioning of facility and bringing the facility to level that can fulfill Regulatory requirements and expected Regulatory Audits.

Desired Profile: Candidates with B.Tech/BE (Mech) / M.Pharma (Industrial Pharmacy) Preferably between 25-30 of age ,Knowledge of Qualification (DQ, IQ, OQ, PQ). Validation of Equipments, Processes, Sound Knowledge of computers, and engineering software's like PRO-engineer, AutoCAD, etc. shall be preferred, Exposure of Regulatory Requirements for Pharmaceutical Industry etc .

Minimum experience: 2 years

Maximum experience: 3 years

Location: Chandigarh, Lalru

Reference: PANRDNAUK

Contact Manager - HR

This serves as an example of the advertisement so as to throw light on the various aspects highlighted in an advertisement during the process of recruitment.

Short Listing Candidates: As a response to the advertisement, people who wish to take up that job send their resumes along with cover letters and this is where the action of sorting out the applications begins. Whatever may be the method of recruitments, the matching of requirement to the resume of candidates' is the first step in short listing the candidates. Further screening is done through group discussions and personal interviews. The number of educated graduates and post graduates are rising, and are useful when fresher are to be recruited, and given facilities for further development and training. This is a matter of policy decision made by the company. The company management and decides the requirements spelled out in the advertisement, as also can be seen from one example above.

Testing as one more filter applied when the supply is more than the demand, which is the case in Indian scenario for most of the jobs. This perception gets modified the moment one thinks of sector specific workforce requirement. The supply is not more for specific demand in terms of categories spelled out for biotech. This can be further elaborated by saying that, the supply of graduates, post graduates is more, but the specialized nature and requirements of biotech field makes the supply of appropriately qualified and experienced candidates limited. As there is no

control over the application process in the sense that any one who feels that s/he is suitable for the advertised position, is free to apply. HR department and particularly the staff engaged in recruitment are overloaded with the number of applications and resumes to be sorted out. This involves both cost in terms of time, money and other resources. This is inevitable and one has to sort all the applications at receiving end whether it is done by an employment agency or staff from HR department.

So as to make the selection process more objective and goal oriented, as the advertisement specifies requirements, the testing process provides another very useful filter for selection of candidates from the vast pool of applications. Depending on the function for which the candidates are being recruited, appropriate testing mechanism like General intelligence and other aptitude tests are used. Though this is a known method, it adds to expenses. Still many managers are of the opinion that these should be used judiciously and they are very useful for further short listing the candidates. On the whole, as a conclusion, aptitude or psychological testing is rare in biotech workforce recruitment in India.

Group Discussions and Personal Interviews: This process provides an opportunity for the HR staff for personal interaction and observation of behavioral patterns and responses of the candidates in groups, and then as an individual. In group discussion the qualities like leadership, communication skills, cooperation, adjustment, problem solving, creativity etc can be evaluated in a behavioral sense. In this process, involvement of company staff from the concerned department, for example production, marketing, finance, etc. is necessary and useful from the point of view of judging the suitability of candidates in the team which may already be there. Depending on the number and type of vacancies, the ranking of the candidates helps the selection process, for selecting the candidates for personal interviews. This process of group discussion is

followed by more than sixty percent of companies and others follow that while recruiting fresher.

Personal Interview: This is one procedure which is followed by all the companies, without exception. Though the concept of best fit is more theoretical, there are practical ways through which one can find a best fit in the sense a good match for a given position. All the discussion above is pertaining to the same point, so far as recruitment methods and process is concerned. It was clear from the responses of companies that personal interview is followed by 100% of companies. Personal interview is normally conducted in a structured or unstructured way. The panel for interview normally is headed by the department head with members from HR. Personal interview is a process for individual assessment and validation of the things written in resume. This makes the process of selection more reliable and transparent both for the company and the candidates, is what almost all the managers expressed.

Factors Affecting the Recruitment Methods and Process:

For recruitment, when the **internal source** is used it becomes a precedence and a policy matter. Other employees are motivated to develop themselves by targeting their individual career development in and with company. This suggests that, beyond entry level positions, many of the positions are and can be filled through internal sources. This may not be possible in some situations where a new technological input or other expertise, not available within the company is necessary for the position to be filled in. These aspects are taken care by the policies and procedures in the course of maintaining employee relations, by most of the companies. The training and development needs of internally recruited candidates are known, through assessment methods like performance appraisals.

When **external sources** are used, irrespective of the source, the method can have a short term or long term effect on the HRM process. The

method has to choose candidates which are trainable and capable of handling the tasks in future. Both skills sets and behavioral attributes of such candidates may require modification and hence training for development.

One way of circumventing this situation, as expressed by HR managers is- rigorous selection procedure for finding best fit is necessary. After that an induction of the new candidate in the company is of great importance. Induction helps the candidate for better adaptation and adjustment with the existing employees and work culture of the company.

The selection of the unfilled position has to be accomplished keeping in view the long tenure of those skill sets and competencies required by the company. This involves recruitment costs as well as if there is an employee turnover, (sometimes it is attributed to mismatch or mistakes in the selection) then it increases the cost per employee for the company. This also has an effect on productivity which could be affected adversely. This is because of new inductions and training, which is a time consuming process.

Biocon - Employee Costs for 2003 and 2004 in Rs million

	02-03	**03-04**	**Change**
Total Employee Costs Rs Million	382	457	+75
Employee nos. (average)	663	867	+204
Avg Revenue Per Employee	4.3	6.3	+2
Avg PAT Per Employee	0.7	1.6	+0.9
Avg cost Per Employee	0.6	0.5	-0.1
Employee Turnover	9%	7%	-2%

In chapter V, in the case studies, in the case of Biocon, it can be seen that the employee turnover and cost per employee are changed for two years under consideration. This reflects efficiency in recruitment as well as in retention measures. Retention has been discussed next.

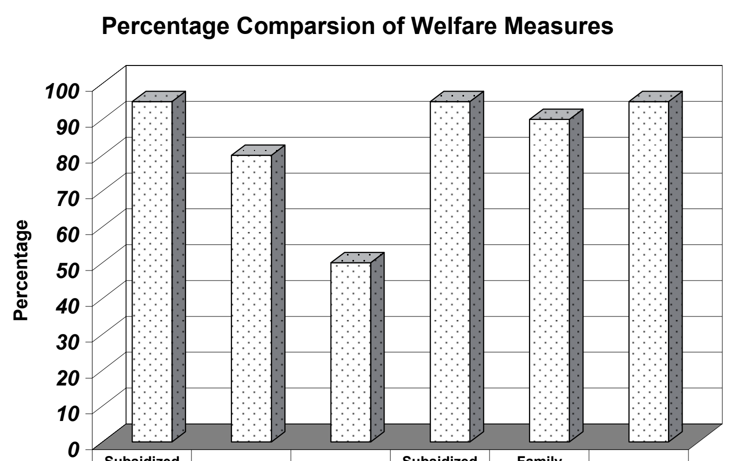
7.1.2 Retention

Retention process is one of the important aspects of HRM which affects the HR planning process. In the measures of retention, welfare measures, career growth opportunities and salary of the employee, contribute to a great extent. Along with this, the work and behavioral culture in the organization are also motivators which induce an employee for staying with the company. The employee will not leave the company unless any other personal reason forces him to leave the company.

Enquiry about the welfare measures with the companies was done and the analysis of the responses is presented below.

Workforce welfare practices followed by companies were obtained through enquiry about two types of measures. Fig. 7.2 presents the comparison of welfare facilities.

Fig. 7.2 Comparison of Welfare Facilities



	Subsidized food at unit canteen	Recreation facility at unit	Health club at unit	Subsidized transport facility,	Family welfare schemes	Medical Insurance
Percentage	95	80	50	95	90	95

Part A – The analysis of items no 1 to 6 is made since they pertain to welfare Practices.

Table 7.2 Welfare Practices

Facilities	1 Subsidized food at unit canteen	2 Recreation facility at unit	3 Health club at unit	4 Subsidized transport home - unit	5 Family welfare schemes	6 Medical Insurance
No. companies	18	15	10	18	17	18
Percentage	90	75	50	90	85	90

Subsidized Food at Unit Canteen: More than 90% of companies provide this facility. Provision of food, during lunch, or dinner break, breakfast and hot and cold beverages etc. puts employees in comfort zone. Companies in IT sector are becoming role models for providing welfare measures and creating comfortable atmosphere at workplace. Food and drink is one of the basic human needs, as Maslow has mentioned in his hierarchy of motivational needs. Provision of good canteen facility at workplace has very positive effect on retention and employee turnover reduction.

Recreation Facility at Unit: Life in 21st century has become very fast. The competition and pressure at work and life in general induces stress, both physical and psychological. Biotech work is more knowledge and technical skill oriented. All the people need to be very vigilant while following different procedures and protocols in biotech R and D, biomanufacturing and related operations. Managerial level employees have to monitor operations with the help of stringent regulatory and international standard norms. Recreation for 10 minutes in the form of a table tennis game, walk on a treadmill, or just a walk in clean and fresh air on the jogging track is very refreshing, and one of the good measures for stress management. 80% of biotech companies provide recreation facilities. This also provides opportunity for people to meet informally and in a stress free environment. This fosters creativity and is required for being innovative in the work.

Health Club at the Unit: Increasing use of technologies has changed life style. The element of physical labor and activity has become minimal. Human body needs to take regular exercise for remaining healthy and fully functional. Life at work and home has mostly become sedentary with the proliferation of computers and use of Information Technology. With this Health club at workplace has become a necessity in modern life. It's another very good motivator and 50 % of companies have reported that they have these facilities for their workforce.

Subsidized Transport Facility- To and Fro from Home:

Metropolitan development has increased the size of industrial cities and commuting has become time taking and strenuous. If workforce is picked up for work, dropped at workplace and then again back home, it's a good solution to the problem of commutation. 95 % of companies provide this facility at subsidized rates. It has become a normal facility now, as the industrial estates are developed away from main city.

Family Welfare Schemes: In addition to employee, his or her family members are also covered under welfare measures like community development, prizes and recognition for meritorious students, and get together functions; with company initiatives, provide a chance for socialization and increasing integrity. 90% of companies have reported having such schemes.

Medical Insurance: Insurance against unpredictable events is an accepted way of life. In working life, workforce may be exposed to more hazards than normal simple life. Cost of medical treatment is increasing. Work situation provides an opportunity for group medical insurance. 95% companies have subscribed to this.

From the above discussion it can be concluded that the welfare practices are sufficient in biotechnology companies for retaining the employees. All the Companies Practice all 6 Categories.

These provide good motivation. The companies are already facing the problems of inadequacy in supply position of right type of manpower and therefore it seems that the retention of present manpower is very pertinent for them. Part B responses are tabulated in Table 7.3 Educational Benefits.

Part – B – Items nos. 7 to 10 relate to education.

Table 7.3 Educational Benefits

	7 Complete tuition fee reimbursement	**8 Partial tuition reimbursement Pl. specify %**	**9 Reimbur- -sement for Workshops**	**10 Complete paid leave/Sabbatical**
No. of Companies	16	4	16	12
Percentage	80%	20%	80%	60%

Complete Tuition Fee Reimbursement: 80% of companies provide this facility for advancing in biotech, technical and managerial education. This is an excellent proposition for fresh graduates and post graduates who want to work and develop the career. Part time or distance learning management courses or web based leaning in regulatory affairs etc. are some of the courses considered under such schemes. 20 % companies provide partial reimbursement.

Reimbursement for Workshops: For knowledge and research skill based working, such as biotechnology, workshops and seminars provide good opportunities for reinforcement, advance learning and networking outside the company. Attending workshops and seminars, and actively participating in them keeps employees informed about the latest development in the field.

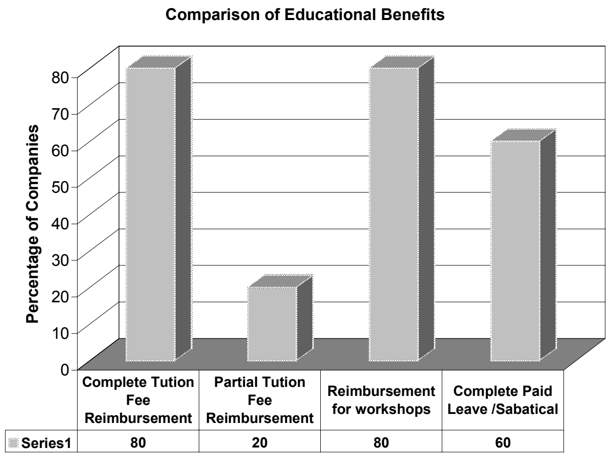


Fig 7.3 Comparison of Educational Benefits

Their contribution and participation in such events, adds to the company image. 80% of companies practice this and for R and D and technology based company this expense has threefold value. Development of employees, retention motivation and depending on laws, tax benefits!

Complete Paid Leave/Sabbatical: Biotechnology is a fast emerging technology. Scientists may be required to work in research institutions on research of latest origin related to industry's strategic focus. In such cases it has become a requirement, which used to be a prerogative of professors and academic research scientists. 60 % of the companies have this provision, which is a great career booster to deserving candidates.

This shows that majority of the companies spend money on education so as to develop career and help retention. This provides career development opportunity for employees and they can plan and look forward to the promotion ladder.

Generally, when the companies are in their infant stage, they concentrate more on operational areas rather than HR issues. But the data

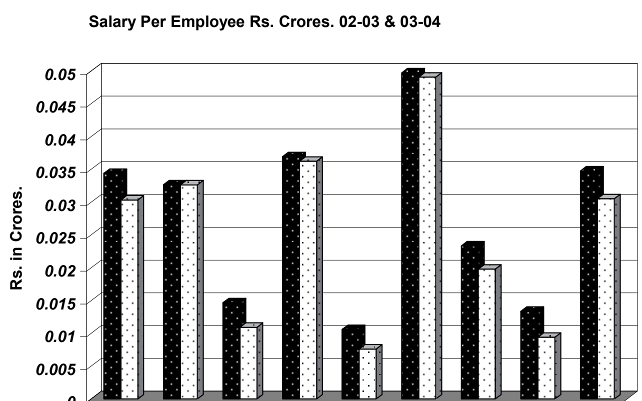
reveals a different trend in biotech business as regards provision of welfare facilities and educational support. The reasons for providing sufficient welfare and educational facilities are as follows, in spite of the stage of business.

a) There is a shortfall of qualified manpower, which is a particular problem of this sector.
b) The impact of globalization and competition have taught the industry to understand the importance of evolving and following good HR practices for retaining the workforce.
c) This reduces workforce turnover, cost per employee in the long run and improves productivity in terms of quality and quantity.

Analysis of Part A and Part B suggest that:

"The welfare practices and educational benefits offered are considerable"

Salary and other expenses: The graph of comparison of salaries in Crores, for the year 2002-03 and 2003-04 is displayed for the purpose of analysis.



	Biocon	Serum	Panacea	Nicholas	Venkys	Wockhardt	GlaxoSmithKline	Krebs bio	Syngene Int.
■ Salary / Employee 2002-03	0.03441	0.03265	0.01467	0.03695	0.01059	0.04973	0.02334	0.01337	0.03476
□ Salary / Employee 2003-04	0.03033	0.03264	0.01093	0.03627	0.00761	0.0491	0.0198	0.00941	0.03055

Fig. 7.4 Salaries per Employee Rs. Crores, 02-03 & 03-04

As can be clearly seen from the graph (Fig 7.4) that there is a decrease in average salary for almost all the companies, (for which the information about salary was made available for these two years under consideration.). It has been seen in the beginning of this chapter that the manpower trend is on increasing and the total expenses towards salary have also increased. The decrease in average salary is explained by mangers saying that, the category of employees where salary per employee is less have increased in number and that explains the decrease in average salary per employee.

Table 7.4 shows the comparison of company wise salary expenses for the two years under consideration, and the percentage change in the same. (It is on increase – that's the trend)

Table 7.4 Comparison of Salaries

Code	**Salaries Rs. Crores**		**Change**	**Change %**
	02-2003	**03-2004**		
1	20.65	27.05	6.40	31.03%
2	56.00	63.00	7.00	12.50%
3	20.54	21.8605	1.32	6.43%
4	73.9	108.82	34.92	47.25%
6	19.07	20.86	1.79	9.39%
7	114.388	171.582	57.19	33.33%
8	112.05	113.3	1.25	1.12%
13	3.88	5.88	2.00	51.55%
15	84.1	97.4	13.30	15.81%
18	5.9804	8.0962	2.1158	35.38%

This is made clear by the increase in salary expenses in the year 2003-04 as compared to that of 2002-03 as seen from the data in the table and graphical representation of the same in fig. 7.5

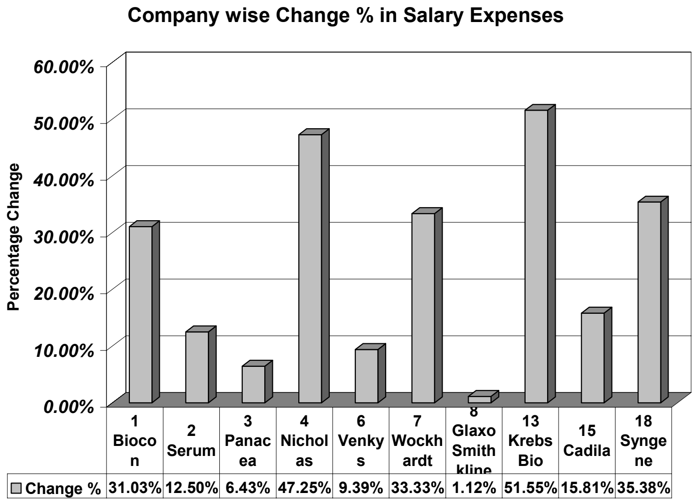


Fig. 7.5 Change % in Salary Expenses in 03-04 (base 02-03)

The comparison reveals that for all the companies as the expenses for salary have gone up. The range is from 1.12 % GlaxoSmithKline to highest 51.5% - Krebs. The other companies having about 30% are Biocon, Nicholas, and Wockhardt.

For the analysis of retention process, the motivators as discussed above, in selected biotech companies are considerably good. Salary is one of the factors affecting retention. Minimum or no turnover of employees due to any cause has a good effect on the planning process, in the sense that, in spite of the competition there is not a great amount of turnover in the workforce as was shared by HR managers of all the companies.

When discussing HR in action, the training and development activity is the most important activity, besides actual work. Actual work is the main purpose for which human resource is planned, recruited, hired and retained. Performance evaluation and need for change management are major factors affecting the HR activities in the arena of training and development. The Human resource development for biotech companies

was studied and observations and critical analysis of the same is presented.

7.1.3 OD-Change Management & Training and Development

As has been explained in chapter IV, the systematic analysis of learning requirements to ensure that employees possess the knowledge and skills to perform satisfactorily in their jobs or to advance in the organization, leads to effectiveness of HR management. This provides inputs necessary for designing and structuring development activities, and scheduling training programs. Performance appraisal, feed back from employees, suggestions from forums like quality circles etc. are always used as a basis for training and development, and these biotech companies are no exception to this process.

Biotech companies recruit qualified workforce using methods and procedures discussed in detail in the section III Human Resources in Action. That provides information about entry level training needs.

Entry Level Training Needs: As it was explained there in chapter IV, the skill sets requirement for biotech is both technical and managerial. The areas in which the recruited candidates need training are identified during the initial phase of their employment. Supervisors make a report in terms of appraisal of their performance and training needs for necessary skills, keeping in mind the skill standards acceptable to a company, are listed out. The duration for which the training has to be provided varies for various skills and adequate time has to be devoted for that purpose. About 80 % of the companies expressed that fresh graduates and post graduates, need training for the period of six to 12 weeks before they are put into regular job without much guidance and supervision. This is because; there is a difference of scale of operations (as was explained about Lab scale and production scale in the chapter II.) Besides, the academic and professional environments are different and the behavioral habits have to be modified and some newly induced, which takes some time.

Ongoing Training: As and when there is any change in any process, whether management process or manufacturing process, or technical R and D process, to cope up with the change, training is a very important tool for organization development, leadership development and team building.

Training is defined as a process of changing employee behavior pattern and or attitudes through some type of structured activity, which provides experiential learning. This is facilitated by an experienced facilitator/trainer. In other words, training denotes efforts to increase employee skills on the present jobs.

Development refers to efforts directed towards improvements related to future jobs. Development programmes are designed to educate employees (which are human resource) beyond the requirements of present job positions. This is in order to prepare them for promotions and also enable them to take a broader view of their role in the organization. Part of this process begins in about 95 % of biotech companies by an induction program. Thus the objective of the process of training and development is to increase the ability of individuals and groups for forming effective, efficient teams. In addition to this, leadership development provides motivation for these teams to contribute to the organization’s mission effectively.

For the purpose of this study, a general study for understanding of Human Resource Development activity is carried out, in the context of Human Resource Planning. As has been referred to in the earlier part of this chapter, this aspect is also tied up with internal sources of workforce supply.

The biotech businesses are of recent origin and that the rate at which new products and services are increasing make it essential for existing companies to develop the skills and competencies for facing the new

challenges emerging in this process. This is for augmenting the human resource for converting into internal source for new or higher positions.

In order to study the state or status of affairs as regards training and development, following two types or methods have been selected as they represent the most common methods usually followed.

1. Apprentice Training
2. Orientation and Reinforcement of Technical and Managerial Skills and Competencies.

1. Apprentice Training

In this chapter, while discussing recruitment, the issue of recruitment of technical and non technical trainees was discussed. The percentage of technical or non technical trainees, in the total trainees recruited is indicative of the category of people which are being planned for, and the training and development needs of both the categories must be catered to. As has been mentioned in chapter IV, people with graduate, post graduate degrees in science are required for working in the research and development and, for manufacturing, people with only a high school diploma or college education are required. From the management trainee's point of view, they come with management degrees with specializations in area like HR, finance, Marketing, production and so on.

Observations

Almost 100 % of the companies recruit trainees. The contention behind recruiting trainees is, it is an advantage that they are raw, the first industry exposure they get is that of biotech when they start working; and it is easier to shape fresh minds.

Departments (Manufacturing Aspects)

1. Research & Development

2. Production

- Chemical synthesis or cell culture
- Purification
- Formulation
- Final doses form, Manufacturing and filling

3. Support Function

- Manufacturing Support
- Quality control, Quality Assurance
- Validation

The typical training programs for apprentice training to be organized are as per the organizational set up described in chapter III. The various departments for the manufacturing functions are reproduced here for ready reference.

Trainees are recruited for the other functions like regulatory affairs, clinical affairs, Marketing, Finance, Human Resources, Licensing /Administration, Project Management, Purchase etc. The skills and other training inputs are of course decided by the final job profile of the candidate, recruited as trainee. The tasks of a bioscience specialist, listed in table 3.2 in chapter III provide a set of typical skills to be considered for trainees in the manufacturing and support function operations. The reader is requested to refer the same for details. Here the job function are repeated as ready reference,

Job Functions

A: Perform Tests /Assays

B: Manufacture Products

C: Obtain Specimen of Materials

D: Process Materials

E: Control Inventory

F: Maintain Equipment and Facility

G: Observe and Document Safe Practices

H: Comply with current Accreditation and Government Regulations

I: Maintain Quality Assurance

J: Evaluate, Document and Report Results

K: Communicate and Document Information (written, Oral, Electronic)

L: Perform Initial Research

M: Care for Research Animals/Plants

N: Maintain Professional Competency

This facilitates reminding the reader of fact- The inference is that the training requirement in biotechnology companies is multidisciplinary.

The training calendar typically has to have an induction programme. This initiates the new entrants in the company. A senior employee with HRD responsibility normally delivers and facilitates this process of induction. It involves familiarization of new candidates with company's vision, mission, operations and work culture etc. This overall picture is for motivating them and invoking their interest and learning potential.

It's a choice of the HR department whether they want to give them behavioral inputs through structured activities. This is useful in building necessary behavioral skills such as, self development, basic interpersonal communication, understanding others, cooperation and working in teams. These are normally organized for cohesive groups. That means a group of

people which is going to work in a functional team like production, support etc. This facilitates simulation exercises, like role play and helps in development of new entrants.

After this the phase of on the job training begins. A group of new apprentices is given charge of to a senior member of a working team. He becomes their mentor. He gives instructions both in the form of written documents and verbal instruction for carrying out tasks. As a mentor he is supposed to structure this activity for monitoring and evaluation. By the end of the training, HR gets comprehensive report about the progress of the new entrants. Feedback from trainees about the content and delivery is also obtained. This is the beginning of performance appraisal.

Problems and Difficulties in Apprentice Training

A) Corporate Level

For apprenticeship training, at corporate level it's a question of satisfaction of legal requirement as per the apprentice training act. For biotech companies this does not pose a problem as such as the trainees recruited are given stipend and facilities and those who are found suitable after apprenticeship training are absorbed in the regular employment. The budgetary provision for apprenticeship and other training is done centrally at corporate HRD level.

The difficulty arises when there is an unplanned requirement of trainees and the question of facilitators and mentors sometimes poses a problem. The solution typically consists of shifting some competent employees in the role or retains external consultants. Getting external consultant is a difficult proposition. This is because biotech is new and emerging.

The induction material like booklets, audiovisuals, videos and films required for training is a responsibility handled centrally by corporate

HRD for all the biotech companies. The training may be conducted division wise, but to keep the standard uniform the resources are provided centrally.

B) Trainee Level

Trainees are new entrants. It is their enthusiasm for learning and anxiety of adaptation to new environment sometimes creates difficulties. The problems of commutation, dress code, culture of the organization are some of the behavioral difficulties the trainees face. There is also a vast difference in the scale of operations, strict regulatory, QA, and QC norms, new procedures like GMP, GLP and OSHA are some of the major changed situations faced by the trainees. This need for paradigm shift creates excitement and anxiety in their minds. It is the mentor who actually has to be careful and vigilant for consolidating the effects of training.

C) Organizational Problems

A look at the job functions of a Bioscience technical specialist listed above makes it easier to comprehend the organisational difficulties the training department has to circumvent. It is a tight rope walking exercise, because the production targets have to be achieved and there has to be accommodation possibility in different teams for inducting new entrants for familiarization of tasks. The nature of biotech operations is multidisciplinary and demands a special working environment, viz. sterilization standards, cleaning, ventilation and air conditioning etc. These conditions are inevitably required for carrying out the biotech processes.

The problem of training facilities and facilitators for technical subjects has specially been mentioned by many senior managers and they pointed out some areas where they find difficulties in procuring external trainers. The areas in which the number of companies find difficulty in locating external trainers and facilities are tabulated in table 7.5

For the purpose of understanding the difficulty the areas are listed in Table 7.5 as responses of % of companies while analyzing the issue.

I. 100% of Companies – DNA Sequencing, DNA Synthesis, Good Clinical Practices, Good Laboratory Practices, Cell/ Tissue Culture, Bio Safety Guidelines, QA/QC Procedures, Good Manufacturing Practices, Sterile Techniques, Instrument Validation, IPR Related

II. 90% of Companies – DNA Isolation, RNA Isolation, Immuno-Precipitation,

III 80% of Companies – In Vitro Transcription, Recombinant DNA Technologies, Imaging, Polymerase Chain Reaction, ELISA, Image Analysis

Table 7.5 Technical Skill Areas - Difficult to Source Trainers and Facilities

	Skill and Competency	**Y**		**Skill and Competency**	Y
01	DNA Sequencing	**20**	21	Sterile Technique	**20**
02	DNA Synthesis	**20**	25	*In vitro* mutagenesis (site directed)	**12**
05	Good Laboratory Practices	**20**			
06	Good Clinical Practices	**20**	26	Hybridoma Techniques	**12**
07	Cell / Tissue culture	**20**	27	Antibody Production	**13**
08	DNA Isolation	**18**	28	Instrument Validation	**20**
09	RNA Isolation	**18**	29	Bioinformatics	**16**
10	*In vitro* Transcription	**16**	30	Image Analysis	**16**
11	Recombinant DNA	**16**	31	Basic Animal Care	**12**
12	Live Animal Handling	**10**	32	Plant Biotechnology	**03**
13	Bio-Safety Guidelines	**20**	33	IPR Related	**20**
14	QA/QC Procedures	**20**	34	Mutagenecity Testing	**13**
15	Imaging	**16**	35		
16	Southern **B**lotting	**15**	36	*Word Processing*	**0**
17	P Chain Reaction (PCR)	**16**	37	*Spreadsheet*	**0**
18	ELISA	**16**	38	*Database*	**0**
19	Immuno-Precipitation	**18**	39	*Presentation, Graphics*	**0**
20	Good Manufacturing Practices (GMP)	**20**	40	*Groupware, IT*	**0**

IV 75 % of Companies – Southern Blotting,

V 65 % of Companies–Antibody Production, Mutagenecity Testing

VII 60 % of Companies- In vitro Mutagenesis, Hybridoma Techniques, Basic Animal Care

VIII 50% Companies – Live Animal Handling,

IX 15 % of Companies- Plant Biotechnology Techniques

This is mainly because as the biotechnology companies are new and there is no infrastructure as yet in terms of biotech parks etc. University departments and other R and D laboratories working in the field of biotechnology just have enough facilities for their own work and this extension activity is not possible for them in the present infrastructure as well as organizational constraints.

7.1.4 Management Skills and Competencies

Management skills and competencies mean the ability to effectively manage to get work done through a team of people. The work is done to satisfy the organizational objectives efficiently. For the purpose of present study the managerial skills and competencies are described using sets of attributes necessary for being effective. Another part of managerial skills and competencies is related to specific function, like Marketing, Production etc.

For Identifying Managerial Skills and competency and making Training Need assessment, the training needs for entry level candidates recruited by the companies were taken into consideration. Then the needs for reinforcement are considered subsequently. The description of need of skills and competencies enquired about is as follows:

The HR managers in biotech companies were requested to specify which item needs to be considered for entry level candidates as training need. The responses are in terms of high medium and low need of

particular items. The entry level candidates are recruited keeping in mind specific function. They have knowledge and skill level for that function to some extent and have to be adapted and reinforced.

With the list of inventory, the responses obtained are presented and analyzed. These responses have been tabulated below and they clearly bring out the training requirement. These needs exist simply because of entry level candidate's non exposure to industrial environment and work requirements in professional set up and experience of the same.

Conceptual Skills are a very important part of Managerial Skills and Competencies and hence the responses are analyzed in detail.

Table 7.6 Responses of Companies –Conceptual Skills

	Conceptual Skills	**High**	**Medium**	**Low**
1.	**Ability to use Information to Solve Business Problems**	80%	20%	0%
2.	**Identification of Opportunities for Innovation**	75%	20%	5%
3.	**Recognizing Problem Areas and Implementing Solutions**	80%	20%	0%
4.	**Selecting Critical Information from Masses of Data**	65%	35%	0%
5.	**Understanding of Business usage of Technology**	95%	5%	0%
6.	**Understanding of Organization's Business Model**	55%	25%	20%

1. Ability to use Information to Solve Business Problems:

It can be seen from the above table that 80% of the companies have responded to this saying the need for this managerial skill and competency training is high in entry level candidates, i.e. management trainees, irrespective of the function they are recruited for. This is quite natural, as

for the management trainees, this is probably the first full time exposure these candidates have to the industrial work situation. Unless any individual has any business and industry exposure, it is difficult to find this skill and competency in entry level candidates. So this conceptual skill training not only will train them in problem solving skills, but they will develop ability and in turn competence for using information for solving business problems, hence the need.

2. Identification of Opportunities for Innovation:

The responses as can be seen are 75 % (High), 20 % (Medium) and 5% (Low). Biotech business is research and development oriented. As has been seen in chapter II all the operations including production can be made more effective and efficient with innovation. Elimination of one single step from a chain of operations, without affecting the results of the operation calls for innovative approach. This is basically a question of aptitude and attitude. The approach in training and development is for attitudinal change.(aptitude is taken care of during recruitment) So along with other competencies, this competency for identification of opportunities for innovation is more crucial for biotech companies, as can be seen from their response. The 5% companies which reported low need explained saying that they have their operations set and optimized so the opportunities at present are less and that explains the low requirement response. But as a conclusion, it must be said that training in Identification of Opportunities for innovation, for developing this managerial skill and competency is another important training need in entry level candidates.

3. Recognizing Problem Areas and Implementing Solutions

The management trainees are normally used to studying for examinations. Though many of them complete summer trainings or internship as a requirement for their academic qualification, their focus is mostly on getting through the examination process. 80% of the companies

have reported that they need training in this area. This is mainly because of scale, style and purpose in industrial work are very different and they need to be oriented for this new working style. No doubt they have to be result oriented, as they were before, but the vision and mission has to be different and the implementation of the solutions has to be 100% practical and effective.

4. **Selecting Critical Information from Masses of Data:**

From the responses it is seen that 65 % companies have reported this to be a training need. This skill and competency has been acquired by the new entrants during the course of their academic study training. Some of the entrants in the companies may be slow in adaptation to new environment and this competency which essentially means good comprehension and quick learning for getting fast results is reported as relatively less required training need.

5. **Understanding of Business Usage of Technology:**

This is where the issue of bimodal skills, referred to in the first chapter, again surfaces. The new management trainees who have biotechnology background, they may be adept in handling the techniques and instrument at laboratory scale and level. They were in the phase of learning then. As 95 % of companies report the need of infusing this skill and competency in the new entrants, it is interesting to note that knowledge of technology alone is not sufficient, but knowing the business usages of the same is very important. This is because, unless any invention or innovation is commercialized, that too in a way so that it can serve the society and provide good returns to the organization doing the business, it doesn’t sustain. For other management trainees, for example, marketing, finance, etc. also so as to understand the commercial aspect of biotech business they have to be oriented into technology. For biotechnology, as it is a technology oriented business, this is a more specific training need.

This managerial skill and competency of "understanding of business usage of technology" is a part of conceptual skills and competency.

6. Understanding of Organizations Business Model:

This competency is needed in the department of strategic management at corporate level. The organizations business model need not necessarily be understood by all people in the management. At corporate level, where the vision and mission of the company is drafted and implemented through the mechanism of delegation, it is very much necessary to have crystal clear understanding of organization's business model. 55% of the companies have said it is high requirement, and it can be inferred from that response, that they are in a stage of development where the business model of the organization has to be understood by entry level candidates also.

The second in order for description of managerial skills and competencies is effectiveness skills. It has been mentioned in the beginning that management means effectively getting the work done. So the importance of effectiveness skill and competency need not be overemphasized. The companies were asked to give their responses as a training need for entry level candidates. The responses of biotech companies to components of the effectiveness skills are as in Table 7.7

Effectiveness Skills: In all there are eleven components of effectiveness skills. The critical analyses of the responses are given in Table 7.7 and have been categorized as High, Medium and Low

1. Contribution to Corporate Mission /Department Objective

It can be seen from the table that the need for this component of effectiveness skill is medium, as reported by 80% of companies. For 15 % companies the need is low and only 5% companies have reported that the training need for this component is high. This reflects the phase of

development of the responding companies.

Table 7.7 Responses of Companies –Effectiveness Skills

	Effectiveness Skills	High	Medium	Low
1.	Contribution to Corporate Mission/Department Objective	5%	80%	15%
2.	Customer Focus	5%	15%	80%
3..	Multitasking, Working at Multiple Tasks in Parallel	70%	20%	10%
4.	Negotiation Skills	80%	20%	0%
5.	Project Management Skills	20%	20%	60%
6.	Reviewing Operations and Implementing Improvements	5%	5%	90%
7.	Setting and Maintaining Performance Standards	5%	5%	90%
8.	Internal : Self and Subordinate Activities	5%	5%	90%
9.	External: Vendors, Suppliers, Business Partners.	5%	5%	90%
10.	Setting Priorities for Attention and Activity	80%	20%	0%
11.	Time Management	90%	10%	0%

The companies which want the new entrants to start the work immediately have expressed the need as high. The normal response is medium which is given by 80% of companies. These companies don't expect the new entrants to immediately start contributing to the corporate mission or department objective. They want the new entrants to be inducted into the atmosphere and work culture and then put them on the job for the desired contribution. The companies which feel that the need is low assume that there is no special need to train people in contributing to

the corporate mission etc. In conclusion we can say that for entry level candidates the training need for this component of effectiveness skill is medium.

2. **Customer Focus:** As can be seen from the table it's a component which has been classified as low, by 80% of the companies. The contention of the companies is that let the entrant get the hang of the operations at the internal level, where enough of activities are customer centered. The entry level candidates hardly need any training in customer focus. It is inferred that the training need of this component is minimal. Where the trainees are recruited for marketing and CRM the response is 15% (medium) and 5% companies consider this as high level need.

3. Multitasking, Working at Multiple Tasks in Parallel

The companies reporting this component as a high training need are 70%. It is understood that management function itself is synonymous to multitasking and in a technology driven business it is more so. Working at multiple tasks in parallel is a need of all the companies and 70% of companies believe in orientating the entry level candidates to this necessary approach in the work culture. Other reported that the integration of tasks can take time and there is no hurry in training them into this necessary aspect of management skill and competency. We can infer from the above that this component of managerial skill and competency is essential and the difference in the level of need is only subjective in the timeline.

4. Negotiation Skills

It is reported by 80% companies that this is a high level training need in terms of managerial skills and competencies. Whatever function one may be working for in management, negotiation skills is one of the most important skill after having acquired communication skills. Many managers from biotech companies out of this 80% consider this as very

important interpersonal skill. For entry level candidates it is more so because they have to negotiate the path of training and have to strive for establishing themselves successfully and this aspect or component of managerial skill has to be considered as a definite training need

5. Project Management Skills

Unless the new entrants are recruited as trainees in the project management division, this is not a training priority. In fact what summer internship project the entry level candidates have completed is taken note of, but project management in itself calls for considerable amount of industrial experience and the need for this training is at a later stage and not at entry level. That's reflected in the responses tabulated above that 20% reported that as a high level, 20% medium level and 60% companies reported that to be low level training need for entry level candidates. The inference from this is "Generally speaking, project management skill and competency is not a training need for entry level management candidates unless they are recruited for project management purpose."

6. Reviewing Operations and Implementing Improvements

The responses of biotech companies for this component of managerial skill and competency is that 90% of the companies have reported this as a low level need for entry level candidates. This skill and competency is required for managerial effectiveness at a later stage of employment and not at the entry level because entry level candidates are very rarely given charge of any work in independent manner. They have to get familiar with the process of operations and after increase in their own proficiency this skill component becomes a training need when they are considered for promotion. The inference is that, for entry level candidates the component of the effectiveness skill "Reviewing operations and implementing improvement" does not constitute as a training need.

7. **Setting and Maintaining Performance Standards**

This managerial skill and competency component of effectiveness skill is a requirement of senior level managerial function. People in senior position only can set performance standards, with their own experience and taking stock of global biotech standards, which is a requirement of the market. It is inferred that biotech companies do not consider "setting and maintaining performance standards" which is a component of effectiveness skill, as a training need for entry level candidates.

8. **Internal: Self and Subordinate Activities** and

9. **External: Vendors, Suppliers, Business Partners** also have response similar to that of above. This is true as explained by the companies that the new entrants are yet new to think of subordinate activities or activities related to vendors, suppliers etc, unless they are in to procurement department and therefore the responses can be explained by arguments that these two components viz. Self and subordinate activities and vendors, suppliers and business partners are not high level training needs for entry level candidates.

10.Setting Priorities for Attention and Activity

As new entrants the main responsibility of these candidates is to learn effectively as much as possible and monitor one's own progress for possibilities of growth. For this they need this self management skill and competency in terms of "Setting priorities for attention and activity' in this learning stage also. This skill component and competency do have a different connotation in Customer Relationship Management, Handling vendors and suppliers or even while handling regulatory affairs or administration. As any management position calls for multitasking and handling multiple tasks simultaneously, setting priorities for attention and activity is a reasonably important managerial skill and competency and 80% of companies have rated that as a high level training needs for entry

level candidates, however the context of that level is different.

11.Time Management

Time management is that component of effectiveness skill and competency, without which effectiveness is not possible at all. In fact in his seminal book The Seven Habits for Highly Effective People, Dr. Stephen Cove has mentioned the importance of the time management and it cannot be over emphasized here. Whether one is an entry level candidate, line or staff manager, senior manager or is in the board of directors; Time Management Skill and Competency is a component of effectiveness skill that is of supreme importance to one and all. The response of 90% of biotech companies shows that they consider this as a training need at high level and remaining 10% consider that need to be of medium level. No company considers this effectiveness skill and competency as low level training need even for entry level candidates. It is understood that this is a skill talked about in schools and colleges and people may have done exercises in time management. In spite of that the biotechnology companies have rated this has a high level training need for entry level candidates, because the scope, meaning and implementation is for business purpose and this business requires the competence at a much higher level is what been shared by 90% of the companies.

Table 7.8 Responses of Companies –Interpersonal Skills

Interpersonal Skills	**High**	**Medium**	**Low**
1.Coaching and Mentoring Skills	**5%**	**20%**	**75%**
2. Diversity Skills: Working with Diverse People and Cultures.	**90%**	**10%**	**0%**
3. Networking within the Organization.	**60%**	**30%**	**10%**
4. Networking outside the Organization.	**5%**	**20%**	**75%**
5.Working in Teams (cooperation and commitment)	**85%**	**15%**	**0%**

About the interpersonal skills and competencies the responses received from the biotech companies selected for study are tabulated in Table 7.8

1. Coaching and Mentoring Skills:

This is the first component of managerial interpersonal skills and competencies. These are necessary for senior and middle level managers who are in leadership and monitoring position. When the new entrants are recruited for the function of training and development then this becomes a training need for the entry level candidates. The responses given by the biotechnology companies reflect that about 5% of companies have reported them as high level skills for new entrants. There are two reasons for this as shared by senior managers. First is that the trainees are recruited for the purpose of training and development and second is company culture and organizational set up is such that the new entrants soon will have a mentor. This paradigm is new to the entry level candidates and for them to get used to this set up, simulation exercises provide training in the aspect of coaching and mentoring. Otherwise the need is of low level as reported by 75 % of companies. The inference here is barring exceptional situations Coaching and mentoring is not a training need for entry level candidates.

2. Diversity Skills: Working with Diverse People and Cultures

As can be seen from the responses of the companies, 90% of the companies consider this component of interpersonal skill as a high level interpersonal skill for entry level candidates. This is because, biotechnology needs diverse knowledge and skill base. During their tenure in the educational institutions students are in a rather protected environment, and also it is not as diverse or multidisciplinary as it is in companies for the purpose of business activity. Along with knowledge and skill diversity of people who will be working together, cultural diversity in Indian situation is inevitable. For making people capable of handling this situation, 90 % companies consider this as a high level training need as mentioned above. 10 % companies consider this as medium level need.

The inference is, for biotech companies this component of interpersonal skill and competency is a high level training need for entry level management trainees.

3. Networking within the Organization

Networking within the organization is considered to be high level training need for entry level candidates, by 60% of the companies. For many it is a part of induction programme. It is necessary so as to understand the organization processes and their interrelation. 30 % companies consider that to be middle level need. This is so because they consider that the new entrants should be totally conversant and competent in handling their own work and they can think of networking within the organization for effective **coordination and cooperation at** a later stage. 10% companies consider this to be a low training need, and this is explained by the nature of work culture and compartmentalization.

It can be inferred that networking within the organization is a training need for entry level candidates at high to medium level.

4. Networking Outside the Organization

According to 75% companies, this is a low level training need for entry level candidates. 20% medium and 5% high account for people who are going to function for interdepartmental coordination for management of vendors and customers. For this reason this component does not become a training need for entry level candidates.

5. Working in Teams (Cooperation and Commitment):

Whether one is an entry level candidate or an experienced person being recruited, working in teams, cooperation and commitment are features of all work cultures. In biotechnology companies also team working cooperation and commitment are very important. In fact it is more important for entry level candidates to train in this aspect of work because

during their educational tenure they do not have to work in teams. Their learning and evaluation of the learning is on individual level. In companies the work has to be done in cooperation with other individuals and commitment for working in teams is important. 85% of companies have reported this component of interpersonal skill as a high level training need for entry level candidates. It can be concluded that the managerial skill and competency component of interpersonal skill "Working in teams (cooperation and commitment) is a high level training need for entry level candidates.

Before getting into critical analysis of function-specific training needs for entry level candidates, the responses for communication skills are analyzed. This is one more component of the managerial effectiveness skill and competencies, as discussed in the beginning. The responses of the companies have been tabulated next.

Table 7.9 Responses of Companies –Communication Skills

Communication Skills	**High**	**Medium**	**Low**
1.Credibility Among Colleagues, Peers and Subordinates	**75%**	**25%**	**0%**
2.Ability to Transform Ideas into Words and Actions	**80%**	**20%**	**0%**
3.Listening and Asking Questions	**95%**	**5%**	**0%**
4.Presentation Skills, Spoken Formats	**80%**	**15%**	**5%**
5.Presentation Skills, Written / Graphic Format	**95%**	**5%**	**0%**

1. Credibility among Colleagues, Peers and Subordinates

The importance of communication skills in creating an image about ones personality is considered to be very important in all social activities. Biotech companies are social groups, converted into functional teams for carrying out various operations, for fulfillment of organizational

objectives. Most of the management schools include personality development workshops as co-curricular activities and in the course of self development programs; communication skills are included in the training program as high priority. So it may appear that the entry level management trainees may not need training in this managerial skill and competency. The responses of the companies are contrary to the expectation. This is because the team working aspect in the companies need establishment of credibility of an individual among colleagues peers and subordinates. This is the reason why 75% of companies have reported this as a high level training need for entry level candidates. The 25 % companies who have put this as a medium level training need think that the quality of work and procedures followed in the company are sufficient to start with for establishing this credibility. From psychological perspective, it is in fact necessary to establish this credibility as early as possible. Though there is a difference of opinion, 75% companies indicate that it is a high level training need and one can go by the statistics and infer that it must be a valid conclusion.

2. Ability to Transform Ideas into Words and Actions

Individuals can be psychologically tested for creativity. That will give an indication about the diversity of ideas and lateral thinking capability of individuals. Ideas are often abstract and it calls for special skills for transforming them into words and actions. In a company work situation, useful ideas, unless converted into a message, for converting that into an action for producing results suggested by the idea, the idea itself cannot be said to be very valuable. This is a very important part of managerial effectiveness skill and competency and 80% of companies consider this being high level training need for entry level trainees.

3. Listening and Asking Questions

The process of proper understanding of a situation and perceptions

of other person about the same are very important for managerial positions. For making appropriate decisions in optimum time one needs to have quick grasp and analytical mind. Listening is one of the very important techniques in effective communication. Listening should be the basis for response. Asking right questions for getting correct description of a situation for identifying problems is the sign of intelligent communication. The responses for this component of communication skill as a training need for entry level candidates is High, by 95 % of companies. Moreover, the entry level candidates are supposed to be learners, where listening and asking questions skill and competency is very important. This is one of the bases for assessment of a person and definitely this is a high level training need.

4. Presentation Skills, Spoken Formats

In biotechnology business, the processes are with live material. The situations are very dynamic and not as static as in industries where non living materials are processed. Presentation skills in spoken format imply spoken communication, with crystal clear ideas and concepts, so as to portray correct picture of the situation in the minds of the listener. Spoken format is one of the methods of presentation, and the speaker has to keep the audience profile, situation, roles in mind along with the objective of communication for that spoken communication to be effective. 80% of the companies have rated this component to be of high level requirement for entry level.

5. Presentation Skills, Written/ Graphic Format

With use of computers and information technology, the quality of graphic presentation has become phenomenal. A picture speaks more than thousand words, is a maxim which is appropriate here. In biotechnology, as the subject is new, the graphic presentation is of great importance. For management training and decision making the importance of graphic tools

for presentation has been accepted world over. 95 % of companies have reported that this component of communication skill which is a part of managerial effectiveness skill and competency is a high level training need for entry level candidates.

Skills Related to Special Functions:

The responses of biotech companies for identifying training need for specific functions in entry level candidates were collected and these responses have been tabulated below, and after the table, critical analysis of the same has been presented.

1. Marketing

Response from 95% biotech companies to this skill and competency for marketing is that, it is a high level training need for entry level candidates.

Table 7.10 Responses of Companies –Specific Function Skills

Skills Related to Specific Function	**High**	**Medium**	**Low**
1.Marketing	**95%**	**5%**	**0%**
2.Human Resource Planning	**80%**	**20%**	**0%**
3.Human Resource Training and	**80%**	**20%**	**0%**
4.Finance, Business Economics	**75%**	**25%**	**0%**
5. Bio Safety	**95%**	**5%**	**0%**
6.Regulatory affairs	**70%**	**30%**	**0%**
7.Licensing / Administration	**60%**	**40%**	**0%**
8. Production	**95%**	**5%**	**0%**
9. Ethics	**95%**	**5%**	**0%**
10. Third Party Certification, e.g. ISO	**80%**	**20%**	**0%**
11. Research and Development	**70%**	**30%**	**0%**

In the section where the recruitment methods and processes have been discussed, it was mentioned that these management trainees are also recruited using campus interview as a preferred method. In spite of this, the reason for this skill becoming a training need is because of special feature of biotech products and services. Marketing function has to place a product in a market and for that the information of all aspects of the product and service are required. Biotechnology uses live plant, animal cells and microorganisms as basic raw material as small manufacturing units. This in itself is novelty for customers and the marketing function has to be specially equipped for making the action plans which will motivate the potential buyer for buying the biotech products and services. This demands for special biotech orientation and hence it has been reported as a high training need at entry level for this marketing function.

2. Human Resource Planning

As biotechnology is new and emerging technology, Human Resource Management is also relatively new. The theoretical background explained in chapter V, explains the necessary conceptual framework. The manpower planning is also known human resource planning. With the emergence of strategic management, the HRM is also becoming Strategic HRM. HRP is now has to be utilized judiciously and it has become more of a strategic planning of human resource. The educational institutions may impart education in SHRM with various techniques for its implementation; the practical aspects still demand special training in the context of biotechnology companies. As shared by the managers, there is a lack of information about the parameters like job specifications and job descriptions for biotech and they rely on the techno structure part of their organization for providing the related information. For making HRP strategically effective, the entry level trainees need be given special training in this function and that is why it is a high level training need for

entry level trainees in biotech companies.

3. Human Resource Training and Development:

Human Resource Training and Development is a function which requires input from all departments in terms of training needs. For biotech companies the training needs for entry level and then change management initiatives are important. Training and development, even if it is in managerial skills and competencies, for a technology driven business like biotech companies, the component of technology relevant to other skills has to be considered while designing programmes for HRD. This creates special requirements, and for the entry level candidate this as a training need of high level, as reported by 80% of biotech companies.

4. Finance, Business Economics

While making project proposals for submission to financial institutions or prospective venture capital firms or institutions, the biotech component becomes significant. As the subject of biotech is new, the entry level candidates need good amount of orientation of biotech. This makes them competent in handling finance and economics of this technology driven business. The inference therefore is that as reported by 75% of companies, finance and business economics is a training need of entry level candidates.

5. Bio Safety

95 % companies have opined that this is a high level training need for entry level candidates. This is a special subject related to hazards associated with biotech operations. OSHA, as related to biotech needs to be considered while designing training on bio safety issues. 95 % companies think this to be a training need for entry level candidates. This is obvious, because though some of the trainees have had exposure to biotechnology, the scale of operations pose different challenges. Keeping

this in mind the inference is the Bio Safety issues become a training need at entry level.

6. Regulatory Affairs

It is the state's job to regulate the affairs of the industry. It strives for balance of effects, in terms of positive effects of products and services provided by the industry to society at large, and the way in which particular industry affects the natural resources, environment etc. keeping in mind the sustainable development. For biotechnology and especially for Bio Pharma the regulatory issues are more stringent than the traditional Pharma business. These issues are not being taught in the educational institutions, which will suit the biotech industries need. 70 % companies have reported this to be a high level training need for entry level.

7. Licensing / Administration

It's a combination of ethics and regulatory issues, is what decides the skill and competency in this managerial function. 60% companies have registered this as a high level, and 40 % companies say it's a medium level training need for entry level. These are industry specific procedural issues. These details have been mostly learned on the job. If entry level candidates are trained in these issues they become capable of handling these issues, which is a requirement of administration.

8. Production

If one refers back to biotech operations and biotech techniques required, it will be clear that the production function is quite typical for biotech. The characteristics of bio manufacturing are not taught in educational institutions. The entry level candidates are exposed to bio manufacturing and production for the first time. Except for the candidates who have exposure to bio-manufacturing and production, this is a training need for entry level candidates as reported by 95 % of biotech companies.

9. Ethics

Business ethics is a topic to which students may have exposure. Biotechnology has special requirements in training candidates for issues related to ethics. Use of human and animal cells for production and modification has raised these issues. So it becomes Bio Ethics in which the entry level candidates need to be trained. This is what is reported by 95 % of companies.

10.Third Party Certification, e.g. ISO

ISO is an international quality standard. It is related to business process and the traceability issues demand that the entry level candidates be trained in these aspects keeping in biotech processes and raw materials and finished products in mind. It has become fashionable now for some educational institutes also to get these certifications. However, for entry level candidates, the issues involved in standardization are new. Unless they are oriented and given the job of implementation of standards, it is difficult for them to learn about the documentation and other procedural aspects of any of these standards. 80% companies have reported this to be a high level training need for entry level candidates.

11.Research and Development

70% of the companies have pointed out this as a high level training need for entry level candidates. This is because special needs of biotech research and development, both in discovery and production processes. The entry level candidates do not have necessary exposure to these functions in the academic set up and thus it becomes a necessity.

Biotech Orientation: From the critical analysis of specific function training need it emanates that all functions in biotech management are to be performed with orientation of biotechnology. This is as shared by managers in the companies and their contention is that, biotech business

operations are more technology driven. They think that human resource in biotech companies need to have skills which are bimodal. The biotechnologists need to have managerial skills and competencies and managerial position people need to have biotech operations orientation.

Biotech Orientation Covers Following Points

a) Biotechnology described from the point of view of management

b) The special features of biotechnology in terms of raw materials and processes.

c) Products of biotechnology, operations, related to company business.

d) Skill sets and other special biotech related issues, like cGMP, GLP. GCP etc.

e) Regulatory, safety, patent and such issues.

These aspects have been discussed in the previous chapters with references to more information.

This covers the critical analysis of management skills and competencies as it is required in the biotech companies. The technical and managerial skills and competencies identified are mainly for entry level candidates. However, learning is a continuous process. New information and issues always emerge during the course of business and initiatives like ERP or SAP for automation of business process also require training and development.

Training and Development of Human Resources

As has been mentioned previously, effectiveness is important in management. The reinforcement of effectiveness skills and necessary technological orientation for management are necessary aspects of management development. The management development is three fold.

a) Development process focused on effectiveness

b) Effective learning process and

c) Effective managerial behavior

The various technical and managerial skills have to be reinforced by way of training and development programmes organized in following ways

1. Internal training programmes by in house faculty
2. In house programs with external facilitation
3. Organized outside by the company with internal monitors and external faculty.
4. Outside organized programs with external faculty
5. Few individuals sent for longer period to other institutions for specialized training related to biotech business, in the country or overseas.

The responses of the companies for enquiry about training programs, the difficulties encountered in getting training providers, availability of facilities for special programs demanded by biotech companies etc, are discussed below.

1. Internal Training Programs by in House Faculty

It is understood from the previous discussions that the biotechnology techniques are common for most of the applications because of the working at cellular and microorganism level. 80% of the companies have reported that they conduct periodic training programs on the technical aspects of operations. This is mainly because of the nature of processes and end products. For example Biocon has a patented fermentation process, training about which cannot be available outside. Similarly, Mahyco Monsanto has genetically modified seeds, thus the specialized technical requirements are only available within the company itself. So the reason for technical training and reinforcement training or change

management training (in the technical aspects) becomes a company-specific need and for the subject of a proprietary process, confidentiality etc. these programs are conducted internally by internal facilitators. Performance appraisal orientation is one more area, which has been dealt with in this category, as reported by 80% of companies.

Some of the management orientations like, induction of new employees, and restructuring of teams for emerging reasons, are also organized and conducted internally. As mentioned above 80% of the companies have mentioned that they follow this practice.

2. In House Programs with External Facilitation

The behavioral part of effectiveness skills and competencies, with their components as discussed previously is better handled by outside experts. This is so because; internal faculty and mentors have close contact with all the "trainees" and there are opinions formed in the minds of them about faculty. Behavioral training is an area which may start with sensitivity programs, and the inputs from psychological point of view need specialized attention and skill. Almost 100% companies have in house programs for behavioral modification, team building, stress management etc. The programs of this nature (in house with external faculty) also include some technical training, but it is normally of seminar nature and the expert speaker delivers new inputs. This kind of programs are organized and scheduled without disturbing the normal working schedules.

Leadership development and team building are two important programs in this category and about 90% of companies do this with the help of external faculty. The calendar of training event for each company is different and though budgetary provision for time and money has been made, no fix schedule was ready with any of the companies.

3. Organized Outside by the Company with Internal Monitors and External Faculty.

This kind of program provides change as well as an opportunity for exposure to different working environment. These kinds of programs are also known as out bound programs. People, who are chosen for these programs, need to be temporarily replaced for keeping normal working and output in place. 60% of companies have this practice, but the programs are not for longer durations. These programs need employees to be taken away from the workplace and this is not always possible for longer durations. Remaining 30% follow this rarely and 10% have not given any response to this.

4. **Outside Organized Programs with External Faculty**

These are organized on need basis and include programs like GMP, GLP, OSHA, and ISO etc. The mode here is some representative employees are sent for these programs and then they effectively become training facilitators for the purpose of dissemination of training to other employees. 90% of companies follow this practice. 10% rely for such matters on external consultants, retained for these purposes.

5. **Few individuals sent for longer period to other institutions for specialized training related to biotech business, in the country or oversees.**

This situation is routine for all companies and they follow this practice on need basis. Usually a senior level employee is chosen for this kind of training. Integrity with the organization and involvement in the strategic development of the company are some of the requirements. The general response for this query is, this event is necessary, but can not be planed as other events. 80% companies have responded saying they need to follow this once in a while.

Problems and Difficulties

There are areas where companies find it difficult to conduct training even if the need was felt and identified. There are various reasons for this. They include difficulty of service provider, time constraints, and budgetary constraints. Most of the companies suggested that for time and budgetary constraints some programs which can wait, those only are kept pending. These two are policy matters and relate to the corporate level decisions. But there are situations when it is difficult to source trainers with biotech orientation. Following is the list of such programmes with response percentage.

The table 7.10 is represented graphically in fig 7.6 and analysis is presented.

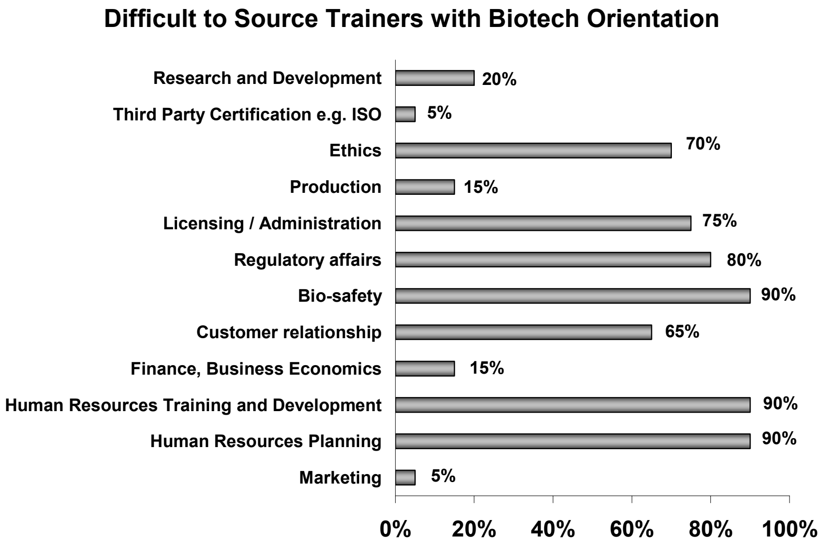
Marketing, Third Party Certification e.g. ISO is the areas where only 5 % companies find it difficult to source trainers. The discussions with managers revealed that, product information and relevant technical details can be delivered by internal faculty. Training in Marketing, is a specialized issue. This is delegated to outside expert for the obvious reasons. Trainers for ISO also are available in abundance. Therefore 5 % company's response is for their own special reasons, like budgetary restrictions and policy decisions at administrative level. Of course the other programmes like GMP, GLP, GCP etc also come under this class and there is relative scarcity of trainers.

Finance and Business Economics, and Production are two areas where 15 % companies find it difficult to source trainers with biotech orientation. The managers in these companies have also said that its because of the internal managerial staff's inadequacy in training and development skills is the reason. In fact they themselves suggested that they should plan some appropriate programs for developing these skills of training for these seniors in production.

Table 7.11 Responses of Companies–Difficult to Source Trainers With Biotech Orientation

Specific Function Skills Areas	Difficult to Source Trainers Y
Marketing	5%
Human Resources Planning	90%
Human Resources Training and	90%
Finance, Business Economics	15%
Customer relationship	65%
Bio-safety	90%
Regulatory affairs	80%
Licensing / Administration	75%
Production	15%
Ethics	70%
Third Party Certification e.g. ISO	5%
Research and Development	20%

Fig. 7.6– Difficult to Source Trainers with Biotech Orientation



Research and Development: Research is a very specialized process, and it requires very special characteristics like, depth of knowledge, lateral thinking, creativity, persistence and meticulous observations etc. A good research and development person may not be able to transfer these skills. In fact, only the people who have aptitude for research will choose this as a career. 20 % companies have reported difficulty in sourcing trainers for this area.

Customer Relationship: CRM is a new emerging branch of sales and marketing functions. It is becoming important in this competitive economies and training in managing customer relationship is becoming increasingly important even for companies with patented products. Training function requires deep insights, and broad spectrum experience on the part of trainer. It is also culture specific. Though customer relationship may be a universal phenomenon, management of the same involves behavioral patterns, which are different in different cultures. Moreover, biotech products are different and even and experienced person in CRM, will have to undergo rigorous orientation so as to become effective in this sector. This is some explanation for the difficulty faced in sourcing trainers for this field as shard by managers of 65 % of companies.

Ethics: The subject of ethics has origin, which is older than origin of business. Ethic involves value judgments, and provides a code of conduct in society. In industrial society also there are ethical considerations. In spite of this background, because bio-ethics is new, its difficult to find trainers. 70 % of companies have reported that there are no trainers for this aspect of HRD. In essence ethical behavior in the context of biotechnology would be to "pursue applications of biotechnology that promise to save lives or improve quality of life. To avoid applications of biotechnology those do not respect human rights or carry risks those outweigh the potential of benefits"[1]

Licensing /Administration: 75 % companies have reported that it is difficult to source trainers. In any regulatory framework, licensing involves a lot of procedural hurdles and checks and cross checks. The bureaucracy can have its idiosyncrasies. In the absence of guidelines for procedures, entrepreneurs and corporations have to take help of knowledgeable consultants for procuring licenses and its administration. These consultants are ready to do the work but are not inclined to train others for obvious reasons. Moreover licensing is not an everyday requirement. This response of 75 % companies reflects on the problems in licensing procedures faced by biotechnology companies while interacting with competent central and state authorities. The expectation of having a trainer for this field may not be appropriate, as this work is a specialized one. On the top of it, because biotechnology is an emerging field in India, the procedure at the central and state government level is also in evolving stage, for example, the national biotechnology policy for India is still in the draft stage.

Regulatory Affairs: This is where the standardization of regulator mechanisms by central and state governments and competent authorities again comes into picture. In fact it can be said that handling of regulatory affairs is a necessary condition in the process of getting a license. Industrial licenses for manufacturing biotech products and services are subject to several central and state government norms. 80% of companies have responded that it is difficult to source trainers for regulatory issues for biotechnology. Reasons for this are almost similar as those which have been mentioned in the paragraph above while analyzing licensing administration.

Bio - Safety: There are consultants and trainers available for industrial safety issue. They are specialized, for example in Oil and Gas industry, Power Generation, Nuclear Power, Engineering Industry,

Aerospace industry etc. They are available because these fields are established now over a period of time. Biotechnology is new. People still are in the stage of fascination about biotechnology. Fascination generates a kind of inertia. In Indian context, beginning of industrial activity in this sector is a vital sign that the inertia phase is over. Still, the infant stage of biotech business in India is responsible for not having proper safety guidelines and procedures for handling live processes. Therefore it is easily understood why 90% of companies have reported that it is difficult to source trainers for bio safety issues, principles and practices.

The observations and critical analysis of the process of human resource planning and development has been presented above. In addition to this, senior managers in companies have shared their views about some aspects of biotech HR in the Indian context. As these are views of hardcore practitioners, they have been included here with comments by researcher for the purpose of analysis and possible emerging suggestions from them. These may provide food for thought and topics for further research, in the emerging industry of biotechnology.

1. Organizational Development

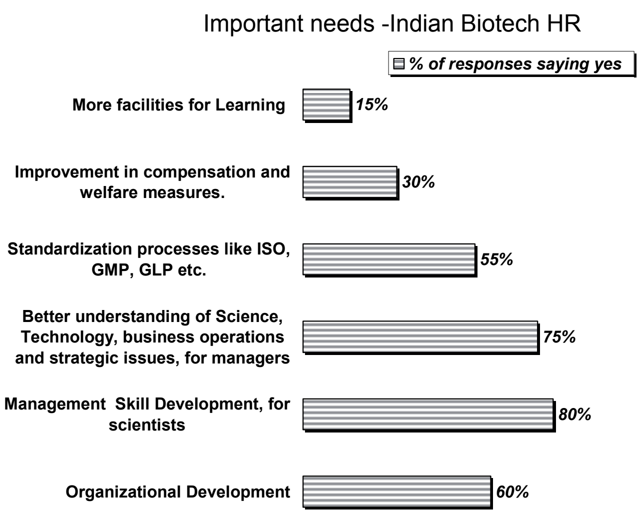
Sixty percent of the companies have responded saying that organizational development is one of the most important needs. As has been detailed in chapter IV, biotech operations, tasks, job descriptions etc provide basis for organization design and development. As the biotech business is in emerging stage, and in India its in infant stage, this is a quite natural need in the course of development of business cycle.

This provides another input, for training needs that at suitable point "organizational development for biotech" or "Evolution of suitable organizational design for biotech processes" for business purpose, has to be dealt with. For existing biotech companies, the managers have clearly shared this need.

Table 7.12 Most Important Needs of Indian Biotech HR

What are the Most Important HR Needs at Present for Biotech Businesses in India?		% of Responses
1	Organizational Development	60 %
2	Management Skill Development, for Scientists	80%
3	Better understanding of Science, Technology, Business Operations and Strategic issues, for Managers	75%
4	Standardization Processes like ISO, GMP, GLP etc.	55%
5	Improvement in Compensation and Welfare measures.	30%
6	More Facilities for Learning	15%

Fig. 7.8 Most Important Needs of Indian Biotech HR



2. **Management Skill Development for Scientists**

While discussing the origin and growth of biotechnology business, it has been mentioned that initially most of the biotech businesses have been started by enterprising scientists. They did the discovery and decided to commercialize it. Commercialization of a discovery calls for special

entrepreneurial management skills. This suggests that biotechnology scientists need to have training in management skills. The R and D scientists who work in companies either in pure R and D or for production research and development, it is useful for business that these scientists are inducted into management skills in the context of commercial business. In India, most of the biotechnology scientists, working in academic institutions or national level centers of excellence represent a potential for Indian biotech sector. According to 80% of the respondent companies, if these scientists are trained into management for commercialization of innovation and management of business, they will better understand the needs of society in term of products and process to be provided economically to society at large. It can be remembered here that in the first chapter the point of bimodal skills points towards the same need.

3. **Better understanding of Science, Technology, Business Operations, and Strategic issues, for Managers**

The mangers responsible for human resource training and development have to take all business aspects into consideration while designing development activities. The goal of all training and development activities is to increase effectiveness in achieving organizational objectives. 75 % of the respondents have communicated that biotechnology business is particularly technology driven. If the managers do not understand science and technology behind the operations which produce products or provide services, then it becomes difficult for them to manage. In this context they have suggested that the manager should have better understanding of relevant science and technology. Moreover, strategic issues and strategic management is relatively new, and it is essential for the managers to know the strategic business issue, at least related to their function. Inference from this is that this becomes a training need for existing companies and a suggestion for institutions for preparing

biotech ready strategic managers for various managerial roles.

4. **Standardization Processes like ISO, GMP, GLP etc.**

The ISO itself is relatively new. GMP, and GLP in the Indian context were not implemented before to the extent they are required in the new globalized market scenario. These are the demands and almost like regulatory norms for biotech industry which is Bio-Pharma driven at present times. For remaining competitive Indian biotech has to initiate the standardization processes like GMP, GLP and ISO, is suggested by 55% of respondents.

5. **Improvement in Compensation and Welfare Measures (30%)**

6. **More Facilities for Learning (15%)**

The suggestions by 30% of respondents that in Indian HR context there should be improvement in compensation and welfare measures can not be said to be representative. This point has been discussed while the issue of retention of HR was discussed. The conclusion of the responses there was the compensation is adequate and welfare measures are considerable in spite of the infant stage of Indian biotech companies. On the same line the response saying there should be more facilities for learning can not be representative, and hence not considered while analyzing responses for evolving suggestions.

7.2 Conclusion

Human Resource Planning and development process in selected Indian biotech companies is studied in details. The presentation in this chapter covered analysis using factors important for planning and development. Sector wise Skill sets and competencies required were enquired into with companies and have been noted down. This has provided skill sets required for Bio Pharma, Industrial biotech and agricultural biotech. Management skills and competencies were also found

out and the training need for both technical and managerial skills was identified at various stages of organization development. The problems and difficulties in providing training, even if the need was there, also were investigated. With the analysis of specific function skills and training need thereof the subject of change management and OD was also researched into for biotechnology companies.

This has provided observations and inferences for HRP and D for Indian biotech companies. After this chapter, the discussions are made regarding the findings and suggestions to different entities in the next chapter.

Chapter VIII
Summary of Findings and Conclusions

8.0 Introduction

In the process of making a summary of findings in the context of the present study it is necessary to **Link Findings** to **Objectives** and **Research Questions.** As have been stated in chapter I, there are **Six Objectives** and **Four Research Questions.** This process of linking will make it clear that how far the research process carried out by the researcher has been successful in achieving the objectives set and questions put forth and summarizing findings and conclusions.

1. Objective Number One-to trace the origin and growth of Biotech Businesses and to gain understanding of Biotech sector in terms of Technology Basics, Main Application, and Extent of Global Spread with Revenue and Employment Generation. This was satisfied through extensive literature review in print and mostly on web sites as has been described in Chapter II Biotechnology in Business – an overview.

2.Objective Number Two-to understand the organizational development of typical biotechnology industry in terms of the different skill sets and tasks required for biotech business process, and

3.Objective Number Three-to review theoretical aspects of HRM as required for developing proper perspective of HRP and D for Biotech Businesses. These have been satisfied through presentation in chapter III Organization of Business Operations and Human Resource Management**.**

4.Objective Number Four of the study**-**to gain understanding of knowledge and skills requirement of typical job positions available in biotech organization, with job descriptions and job specifications and explore experiences from other countries in similar HR issues, has been satisfied by presentation in chapter IV: Knowledge, Skill Sets and Job Positions in Biotechnology Business

5.Objective Number Five needed a backdrop of understanding of Indian biotech scenario. This has been achieved through an analytical review of Indian biotech scenario with case studies of four biotech companies, in Chapter V: Case Studies of Selected Biotechnology Companies. This revealed that Bio-Pharma or health care biotech is in leading position in India. This was supported by statistical analysis of contribution of revenue of different sectors of biotech. Here the spread of biotech businesses across the sector is understood and top twenty businesses are selected for studying. The selection has been justified properly with quantitative data analysis. The revenue and employment trends for the period under consideration (2002-03 & 2003-04) have been compared and it was shown that the revenue and employment of biotech companies selected was having rising trend. The policy of central government is reviewed for understanding policy statements related to the scope of present study. Analysis of Human Capital in India and educational qualification wise composition of employees in Biotech Companies was presented in terms of a pie chart showing percentages of various levels of education from graduation up to doctoral degrees.

Case study and analysis of four company's viz. Biocon Ltd., Serum Institute of India Ltd., Wockhardt Ltd and Maharashtra Hybrid Seed Corporation Ltd have been presented. The four case studies presented are representative, for knowing the Biotech companies in terms of Products, Operations, Market Position and HR Scenario, for example Biocon, showing HR parameters as an illustration of results good HR practices for retention. There is general absence of systematic information about knowledge skill sets and competencies required in Biotech Business etc.

The Research Questions

1. What are the peculiarities of Biotechnology Business sector in terms of Resources, Products, Business Operations, and Organization? and

2. What are the Constraints on this industry in terms of

Availability of Right type of Workforce?

Were answered satisfactorily through presentation in Chapters II, III and IV and V. and the question

3. What are the different aspects relating to Demand and Supply of HR in Biotech sector? This was answered satisfactorily by presentation in Chapter VI: Demand for and Supply of HR – in Selected Biotech Companies.

That presentation in Chapter VI also has created background necessary for developing understanding about the process of satisfaction of objective five-to review and to analyze Human Resource Planning and Development process in selected Biotech Businesses. This fifth objective has been satisfied by the presentation in Chapter VII HR Planning and Development Processes–An Analysis using Factors**,** which also has answered the fourth research question **-**What is the scenario of Human Resource Planning and Development processes followed in Indian Biotech business? Do they Require any New Initiatives?.

6.Objective Six-to suggest ways and means for improving activities of Human Resource Planning and Development in Biotech Businesses has been satisfied by presentation in Chapter VIII Summary of Findings and Suggestions, which is the subject matter of present Chapter VIII. The list of additions made by the researcher to the present fund of knowledge is presented and then the process of making suggestions is explained in the next paragraph.

Process for Making Suggestions: The objective of the study item no 6, undertake to make suggestion based on the research work. They relate to HRP and D activities in the Biotech Business. These suggestions have backward linkage to data analysis and findings as well as the

interactions during meetings with HR and senior managers and the discussions made with them from time to time during the entire journey of the study.

The Biotech Businesses and their HRP and D activities are identified, planned and executed regularly by the managers in the Biotech Companies. However, the various internal and external entities play different and significant roles for happening of them. The researcher has identified them in their importance and priority of suggestions. Only corporate cannot entirely accomplish the needs of HRP and HRD in Biotech Businesses. Therefore the suggestions are made to different entities according to their role with reference to the point, which is common. The entities are

1. Corporate Sector
2. Educational Institutions
3. Other Institutions
4. Government (Apex bodies)
5. Trainers
6. Consultants
7. New Entrants and Trainees

A sincere and honest attempt has been made to make the suggestions which would have the attributes such as

a) Within the Context (to be consistent with the Scope of the Study)
b) Linkage to the Analysis and Findings
c) Feasible and
d) Prescriptive

The writing scheme followed for making suggestions based on findings is as follows. Background on which the summary is presented is briefly stated. Summary of findings emerging from the analysis in Chapters V, VI and VII is presented before attempting to make suggestions. While making suggestions the reference of the observations and finding to which it relates is mentioned briefly. Though it has involved some minor repetition of point in findings while addressing suggestions to different entities, it was thought to be acceptable for making those points available for ready reference before reading related suggestion.

8.1 Summary of Findings

This is a summary of findings emerging from the Chapter V: Case Studies of Selected Biotechnology, Chapter VI: Demand for and Supply of HR – in Selected Biotech Companies and Chapter VII: HR Planning and Development Processes –An analysis using factors

Background on which the Summary of Findings is presented:

I. The global overview in terms of historical growth, extent of spread and socio economic effects of biotech business was taken in Chapter II. There it was seen that the United States of America is the leader and next in line are Canada and UK in Europe. India is in the Asia Pacific region where the Biotech Business is emerging and the contribution of Asia Pacific region to Biotech Revenue and Employment at Global Level suggested that **the Biotech Business in Asia Pacific Region is in Infant Stage.**

In the beginning of the overview, in Chapter II, scientific basics of biotechnology, definition of biotechnology and biotechnology business, special features of biotechnology, main applications of biotechnology, sectorial categorization or classification etc. was also discussed. Against this backdrop, the Indian biotech scenario, and case studies of few biotechnology companies are presented in detail in this Chapter V.

8.1.1 Case Studies

Indian scenario has been presented in the context of global biotech and it is seen that Several American and European companies are facing resource constraints. For increasing productivity one way for them is to develop collaboration with companies with those resources at a lower cost. With its abundant high quality-low cost manpower, India is emerging as a partner of choice.

India's major biopharmaceutical companies are now accelerating efforts to get bioequivalent versions of patented, well-characterized recombinant proteins onto the market before 2005. The small biotech companies are focusing on innovative research, and are picking niches where there is little competition. Bioinformatics companies are other players who are benefiting from an intellectual property driven model.

The four case studies presented are representative, for knowing the biotech companies in terms of products, operations, market position and HR scenario, for example Biocon, showing HR parameters as an illustration of results good HR practices for retention. There is general absence of systematic information about knowledge skill sets and competencies required in biotech business. This portrait of Indian scenario has provided sufficient backdrop for understanding description in chapter III Biotech Businesses- Operations and Organization, HR management in biotech companies in India, and Chapter VI Human Resource Planning and Development in biotech companies.

8.1.2. Forecasting Demand for Human Resources

Forecasting demand for Human Resources implies **How Many People with What Abilities the Company will need in a Foreseeable Future to Remain in Operation.**

The two years, 2002-03 and 2003-04 were chosen for the purpose of data collection and analysis for present study, which are the only data available officially. The inferences which were drawn from the analysis of the data are

1) In the case of each company the number of manpower or workforce employed is on the increase.
2) The increase is substantial and corresponding increase in sales figure is also seen.

This shows the trend that growth in sales turnover of a company is positively related to growth in manpower.

After getting this trend in manpower in Indian biotech companies for the purpose of forecasting category wise requirement of manpower by the companies was analyzed. A list of categories or job covered for projection is as follows

1. Scientist R and D, 2. Engineers (All Departments)

3. Technicians (Skilled), 4. Regulatory/ Clinical Affairs

5. Production (Skilled + Unskilled)

6. Marketing, 7. Finance

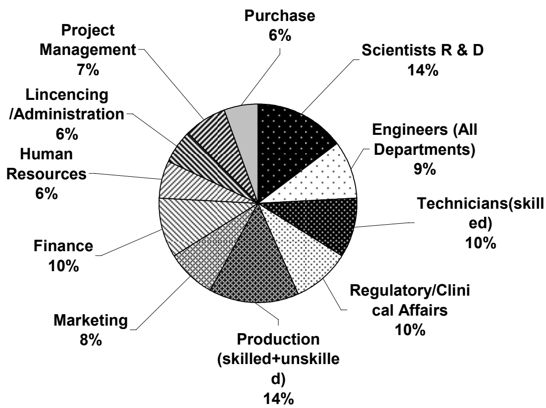
8. Human Resources

9. Licensing / Administration

10. Project Management, 11. Purchase

Observations springing from the analysis of category wise unfilled positions for Indian biotech companies as represented using the pie chart are:

Estimation of HR Demand- Category wise Percentages



1. For all companies there are unfilled positions in one category or other.
2. The maximum percentage is that for two categories:

   R and D (14%) and Production (14%)
3. Regulatory/Clinical, Technicians, Finance, these three are second in line (10%)
4. Then Engineers 9%, Project Management 7% and Purchase, Licensing/Administration and Human Resources are 6 % each.
5. As responded explicitly by management of all companies that the reason behind unfilled position is **Lack of Qualified Candidates, which is No Availability of Them.**
6. By and large the companies do not think that "compensation expected by qualified candidates is too high" is the reason for the positions remaining unfilled.

8.1.3 Supply of Human Resources

For Entry Level Positions, educational institutions are the best source. These are utilized by the company by way of knowing the subjects and strengths

of the student's against their own requirement. Campus interviews, summer placements, internships etc are some of the ways for locating, testing and estimating the capacity of such sources for recruitment of candidates at entry level positions.

For Senior Level Technical and Managerial Positions, placement agencies and consultants is a method of choice. This is done because sometimes this part of the personnel function is outsourced. Another reason for this is keeping confidentiality and avoiding the inflow of many numbers of applications. The population explosion and availability of education produces many no. of graduated, post graduated and doctorate candidates throughout the nation every year. However, this information is not enough. Biotechnology needs people of particular qualification and experience to satisfy the demand, which has been estimated.

The general problems or constraints associated with forecasting of demand and supply of human resources for biotech industries, which forms the **basis of human resource planning** activity, have been stated in the table.

Lack of Appropriate Training and Education facilities / institutions is expressed by 60 % of respondents.

***A4: Matter of Priority**

HR managers in selected biotech companies expressed a need for proper method for working out all the HR planning activities, including those of training and development and the facility should cover all the parameters of HR planning.(20% of respondents)

Lack of succession or replacement planning (80%) Lack of Production and Promotion policy (60% each) and change in technology (80%) are included in factors with short range effect.

****B. 5 Lack of Data Such as Skill Inventory**

Skill inventory for biotech –technical is special. Based on that tasks, jobs, job description and job specifications are necessary for organizational design.

The management skills and competencies also need to be made available for the purpose of planning of HR (80% of respondents)

Factors, Constraints Associated with HRP

No.	Factors Responsible on a Scale of Five Grades	2002-2003					2003-2004				
	1=20%, 2=40% 3=60% 4=80%, 5=100%	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
A	**LONG RANGE Effect**										
1	**Growth of Organization**				√					√	
2	**Budgetary Constraints**	√					√				
3	**Lack of Appropriate Training and Education Facilities / Institutions**			√					√		
4	**Matter of Priority***	√					√				
B	**SHORT RANGE Effect**										
1	**Change in Technology**				√					√	
2	**Production Policy**			√					√		
3	**Promotion Policy**			√					√		
4	**Lack of Succession or Replacement Planning**				√					√	
5	**Lack of Data such as Skill Inventory****				√					√	

8.1.4 HR Planning and Development Process

The factors making the process successful were identified for and during the enquiry are Recruitment, Retention, OD-Change Management & Training and Development, Management Skills and Competency needs, etc. The analysis of the HR planning and development processes using these factors is presented here as findings.

8.1.4.1 Recruitment: For initiating the recruitment process, identification of job skill and competency is one of the primary needs.

The skill set requirement has been listed after collecting the responses from selected companies (to question 9a in questionnaire- see appendix I) and by grouping them sector wise. First the technical skills and competencies are listed in alphabetical order.

Biotechnology Skill Sets and Competencies – Sector wise

Bio Pharma or Healthcare:

1. Antibody Production, 2.Basic Animal Care, 3.Bio-Safety Guidelines, 4.Cell Culture, 5.Column Chromatography, 6.Database, 7.DNA Isolation, 8.DNA Sequencing, 9.DNA Synthesis, 10.ELISA, 11.Gel Electrophoresis, 12.Good Clinical Practices (GCP), 13. Good Laboratory Practices (GLP), 14.Good Manufacturing Practices, 15. Groupware/IT, 16.High Pressure Liquid Chromatography (HPLC), 17.Hybridoma Techniques 18.Immuno-Precipitation,

19. In Vitro Mutagenesis , 20.In Vitro Transcription, 21. In Vitro Translation, 22.Instrument Validation, 23.IPR Related, 24.Live Animal Handling

25. Mutagenecity Testing, 26.Polymerase Chain Reaction (PCR), 27.Peptide Synthesis, 28.Protein Purification, 29.QA/QC Procedures, 30.Recombinant DNA Technologies, 31.RNA Isolation, 32.Southern Blotting, 33.Sterile Technique, 34.Bioinformatics, 35.Image Analysis, 36.Imaging, 37.Spreadsheet, 38. Word Processing, 39.Presentation, 40.Graphics

Industrial Biotech:

1. Bio-Safety Guidelines, 2.Cell Tissue Culture, 3.Column Chromatography, 4.Database, 5.DNA Isolation, 6.DNA Sequencing, 7.Gel Electrophoresis, 8. HPLC. 9. Instrument Validation, 10.IPR Related,

11. Polymerase Chain Reaction (PCR), 12.Peptide Synthesis, 13.Protein Purification, 14.QA/QC Procedures, 15.Recombinant DNA Technologies

16. Spreadsheet, 17.Sterile Technique, 18.Word Processing.

Agricultural Biotech

1. DNA Isolation, 2.DNA Sequencing, 3.DNA Synthesis, 4.Good Laboratory Practices (GLP), 5.IPR Related, 6. Hardening of Plants,

7. Polymerase Chain Reaction (PCR), 8. QA/QC Procedures, 9.Recombinant DNA Technologies, 9. Sterile Technique, 10. Tissue Culture, 11.Spreadsheet, 12.Word Processing, 13.Presentation, 14.Graphics

As a response to question no. 12 in the questionnaire (in Appendix I) It is seen from the data that while recruiting people for specific function, biotechnology companies have expressed a need that for all the functions listed, viz. Marketing, Human Resource Planning, Human Resource Development, Finance, Business Economics, Customer relationship, Bio-safety, Regulatory affairs, Licensing/Administration, Production, Third Party Certification e.g. ISO and Research and Development and Ethics , the entry level candidates need to be given orientation training.

Entry level Training need % for Specific Function Skill

Specific Function Skill	**Entry Level Need**			
A=Always, O=Often S=Sometimes, R=Rarely	**A**	**O**	**S**	**R**
Marketing	21%	58%	21%	0%
Human Resources Planning	11%	63%	26%	0%
Human Resources Training and Development	16%	73%	11%	0%
Finance, Business Economics	21%	58%	21%	0%
Customer Relationship	21%	63%	16%	0%
Bio-Safety	32%	68%	0%	0%
Regulatory Affairs	32%	57%	11%	0%
Licensing / Administration	26%	58%	16%	0%
Production	39%	52%	9%	0%
Third Party Certification e.g. ISO	16%	52%	32%	0%
Research and Development	21%	58%	21%	0%
Ethics	26%	58%	16%	0%

After this the findings from the analysis of recruitment process as responses to question 5 in the questionnaire (appendix I) of selected biotech

companies are presented.

1. There is no special source of recruitment although the environment and technology of biotech businesses is different from engineering or chemical and such other established businesses.
2. Therefore it can be said that "The sources of recruitment and their usage, for biotech and non-biotech businesses are similar"

8.1.4.2 Retention: the extent of welfare facilities and educational benefits offered by selected biotech companies was assessed by responses to question 6 and analysis of responses to the same suggest that

"The welfare practices and educational benefits offered are considerable. The welfare practices are sufficient in biotechnology companies for retaining the employees. All the companies practice all 6 Categories.

The reasons for providing sufficient welfare and educational facilities are as follows, in spite of the stage of business. They are as follows.

a) There is a shortfall of qualified manpower, which is a particular problem of this sector.
b) The impact of globalization and competition have taught the industry to understand the importance of evolving and following good HR practices for retaining the workforce.
c) This reduces workforce turnover, cost per employee in the long run and improves productivity in terms of quality and quantity.

Salary Component of Retention was analyzed using responses of the companies to related part (01) of question 17 and analysis of financial data available from selected companies. The findings are presented below:

The salaries are increasing from 1.12 % to 50%. This increase is good and encouraging for people to take up biotech career.

8.1.4.3 OD- Change Management & Training and Development

The responses to the questionnaire and discussions with mangers provided information and analysis of the same provided findings

The range of technical trainees is from 85% to 95%. The percentage of trainees from non-technical areas like finance marketing HR etc is from 05% to 15%. For emerging nature of the biotech businesses, this percentage is very much in its natural course since the technical requirements supersede the non technical functions.

100 % of the companies recruit trainees. The contention behind recruiting trainees is, it's an advantage that they are raw, the first industry exposure they get is that of biotech when they start working; and its easier to shape fresh minds.

A) Training Types and Needs

1. Apprentice Training
2. Orientation and Reinforcement of Technical and Managerial Skills and Competencies.

- For all new candidates Induction training program is arranged.
- For Apprentice-ship training, category wise training and for technical apprentice's job function wise training need to be provided

B) Job Functions wise Training for Apprentice

a: Perform Tests /Assays,

b: Manufacture Products

c: Obtain Specimen of Materials,

d: Process Materials

e: Control Inventory,

f: Maintain Equipment and Facility

g: Observe and Document Safe Practices

h: Comply with current Accreditation and Government Regulations,

i: Maintain Quality Assurance

j: Evaluate, Document and Report Results

k: Communicate and Document Information (written, Oral, Electronic),

l: Perform Initial Research

m: Care for Research Animals/Plants

n: Maintain Professional Competency

The inference is that the training requirement in biotechnology companies is multidisciplinary.

Problems and Difficulties in Apprenticeship Training, Technical skill areas where it is difficult to source trainers and facilities

The problem of training facilities and facilitators for technical subjects has specially been mentioned by many senior managers and they pointed out some areas where they find difficulties in procuring external trainers.

For the purpose of understanding the difficulty the areas are listed as responses of % of companies while analyzing the issue.

I. 100% of Companies – DNA sequencing, DNA synthesis, Good Clinical Practices, Good Laboratory Practices, Cell/ Tissue culture, Bio Safety guidelines, QA/QC procedures, Good Manufacturing Practices, Sterile techniques, instrument validation, IPR related

II. 90% of Companies – DNA isolation, RNA isolation, Immuno-precipitation,

III 80% of Companies – in vitro transcription, Recombinant DNA technologies, Imaging, Polymerase Chain Reaction, ELISA, Image Analysis

IV 75 % of Companies – Southern blotting,

V 65 % of Companies – Antibody production, Mutagenecity testing

VII 60 % of Companies- In vitro mutagenesis, Hybridoma Techniques, Basic animal care

VIII 50% Companies – Live animal handling,

IX 15 % of Companies- Plant biotechnology techniques

This is mainly because as the biotechnology companies are new and there is no infrastructure as yet in terms of biotech parks etc. University departments and other R and D laboratories working in the field of biotechnology just have enough facilities for their own work and this extension activity is not possible for them in the present infrastructure as well as organizational constraints.

8.1.4.4 Management Skills and Competencies Needs:

Responses of Companies –Conceptual Skills

	Conceptual Skills	High	Medium	Low
1.	Ability to Use Information to Solve Business Problems	80%	20%	0%
2.	Identification of Opportunities for Innovation	75%	20%	5%
3.	Recognizing Problem Areas Implementing Solutions	80%	20%	0%
4.	Selecting Critical Information from Masses of Data	65%	35%	0%
5.	Understanding of Business Usage of Technology	95%	5%	0%
6.	Understanding of Organization's Business Model	55%	25%	20%

Responses of Companies –Interpersonal Skills

Interpersonal Skills	High	Medium	Low
1.Coaching and Mentoring Skills	5%	20%	75%
2. Diversity Skills: Working with Diverse People and Cultures.	90%	10%	0%
3. Networking within the Organization.	60%	30%	10%
4. Networking outside the Organization.	5%	20%	75%
5.Working in Teams (cooperation and commitment)	85%	15%	0%

Responses of Companies –Effectiveness Skills

	Effectiveness Skills	High	Medium	Low
1.	Contribution to Corporate Mission/Department Objective	5%	80%	15%
2.	Customer Focus	5%	15%	80%
3..	Multitasking, Working at Multiple Tasks in Parallel	70%	20%	10%
4.	Negotiation Skills	80%	20%	0%
5.	Project Management Skills	20%	20%	60%
6.	Reviewing Operations and Implementing Improvements	5%	5%	90%
7.	Setting and Maintaining Performance Standards	5%	5%	90%
8.	Internal : Self and Subordinate Activities	5%	5%	90%
9.	External: Vendors, Suppliers, Business Partners.	5%	5%	90%
10.	Setting Priorities for Attention and Activity	80%	20%	0%
11.	Time Management	90%	10%	0%

The data presented in these tables is self explanatory and inferences are clear in terms of high, medium or low need of a given component of management skill and competency.

Responses of Companies –Communication Skills

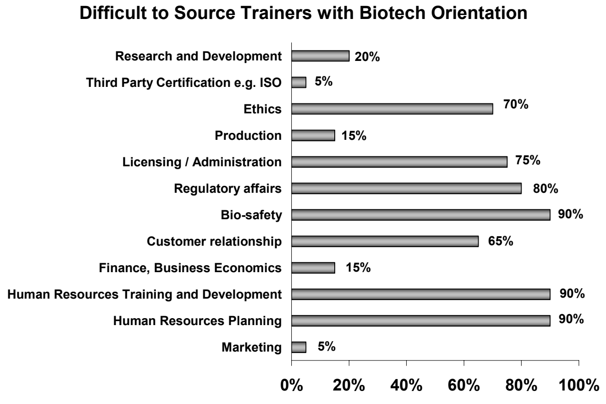
Communication Skills	High	Medium	Low
1.Credibility Among Colleagues, Peers and Subordinates	75%	25%	0%
2.Ability to Transform Ideas into Words and Actions	80%	20%	0%

3.Listening and Asking Questions	**95%**	**5%**	**0%**
4.Presentation Skills, Spoken Formats	**80%**	**15%**	**5%**
5.Presentation Skills, Written / Graphic Format	**95%**	**5%**	**0%**

Responses of Companies –Specific Function Skills

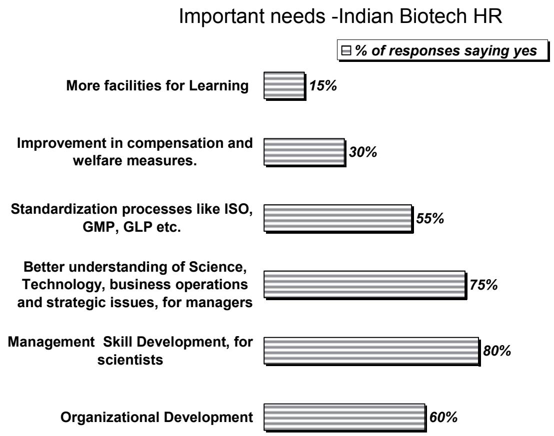
Skills Related to Specific Function	**High**	**Medium**	**Low**
1.Marketing	**95%**	**5%**	**0%**
2.Human Resource Planning	**80%**	**20%**	**0%**
3.Human Resource Training and Development	**80%**	**20%**	**0%**
4.Finance, Business Economics	**75%**	**25%**	**0%**
5. Bio Safety	**95%**	**5%**	**0%**
6.Regulatory affairs	**70%**	**30%**	**0%**
7.Licensing / Administration	**60%**	**40%**	**0%**
8. Production	**95%**	**5%**	**0%**
9. Ethics	**95%**	**5%**	**0%**
10. Third Party Certification, e.g. ISO	**80%**	**20%**	**0%**
11. Research and Development	**70%**	**30%**	**0%**

Problems in Managerial Skills Development



Responses of Companies – Difficult to Source Trainers with Biotech Orientation

Most Important Needs of Indian Biotech HR



The summary of the observations as emerging from the analysis has been presented. Findings based on observation and the work related to objectives of the study and research questions, provides a backdrop for making suggestions to various institutions and organizations, as was mentioned in the beginning.

8.2 Suggestions

As has been mentioned in the previously in this chapter, the suggestions are based on findings and have the characteristics like

e) Within the context (to be consistent with the scope of the study)

f) Linkage to the analysis and findings

g) Feasible and

h) Prescriptive

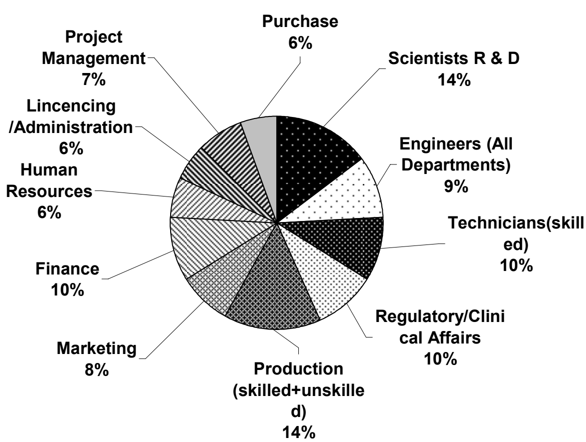
The suggestions emerging from various findings to different players are listed under that player.

8.2.1 Corporate Sector

Suggestion related to findings in HR planning study process for biotech companies it was found **that growth in sales turnover of a company is positively related to growth in manpower.**

1. Corporate offices of biotech companies keep track of sales turnover for monitoring the performance of the company. This finding could be positively used by them. They can proactively find out which category of workforce is responsible for this increase. This key result provides a valid process for Marketing strategy, Manpower for marketing. Marketing and Sales has a backward linkage to other company operations and the strategy can be converted into effective action plan with other resources and particularly for Human Resource Planning. This includes activities from recruitment to training and development. It also involves communicating emerging needs to concerned educational institutions and related agencies for effective implementation of HRP.

Estimation of HR Demand- Category wise Percentages



Biotech companies- can use this method for category wise estimation of demand for their own company. They can follow the simple procedure as outlined below for practical use.

With the help of information about unfilled positions, emerging projects, succession requirements, contingent requirements etc. at the corporate office, companies can make their own workforce planning model. Following steps are suggested as an outline for working out the workforce planning model. It has five major parts.

1. Strategic Direction Setting

2. Supply, Demand and Discrepancies

3. Development of Action Plan

4. Implementing Action Plan

5. Monitoring, Evaluation and Revision

1. Strategic Direction Setting

a) Taking into consideration the corporate vision, mission and objectives, take a review of organizational structure. Evaluate the need for business process reengineering – objectively.

b) Organizational performance measurement is the next step. In Strategic Human Resource Management, the quantifiable measures like employee turnover, employee costs, revenue generation etc are used as score parameters for evaluation of organizational performance. This step requires that HR department is positioned as a strategic partner in the company and not only a service department.

2. Supply Demand and Discrepancies

The information about unfilled positions was the point of beginning. The reasons for those positions remaining unfilled have to be clearly investigated. Then look for workforce trends for calculating projection of the demand. For getting the picture of workforce diversity in the demand in terms of skills and competencies with educational background, a list of sources for the supply of

workforce is necessary. For this purpose assessment of competency and capacity of the various supply sources in terms of quantity and quality standards is necessary. This will make it possible for making a chart of company workforce needs against available skills. This will automatically bring out discrepancies, if any.

3. Development of Action Plan

As has been outlined above, the skill and competencies gaps are clear from step 2. To fill these gaps, a priority list and action plan has to be prepared. This plan should be specific. What types of people are required and when are they required? What financial and infrastructural needs are there? That means setting objectives and developing required HR infrastructure is necessary.

4. Implementing Action Plan

For the purpose of implementation of this action plan, it is necessary to form a team. Various tasks in the action plan have to be distributed. According to these roles, the work has to be initiated. Delegation of responsibility and setting targets is necessary. The tasks involved are assessment of need validation, recruitment, succession planning etc. Understanding of retention strategies is important and restructuring the action plan wherever necessary has to be done.

5. Monitoring, Evaluation and Revision

Any action plan has to be monitored, evaluated and revised if necessary, for successful implementation. It will make easier to assess successes and failures, and making adjustment to the plan. It will also make it possible for attending to the new workforce needs and issues regarding their induction etc.

Finding Factors, Constraints Associated with HRP- related suggestions

Growth of Organization: Growth of the organization is generally a planned phenomenon. In fact when organization grows, generally the manpower requirement increases. The finding indicates that Growth Management can be done more systematically at corporate level. For example formerly TELCO and

now Tata Motors Ltd. has a separate department for handling all issues related to G**rowth** in a very systematic and timely manner. Though in infant stage, the biotech companies need to grow fast in global competitive environment and it is suggested that for attracting and retaining quality workforce, growth management efforts at corporate level should become an integral part of strategic vision and mission of the company.

Lack of Appropriate Training and Education Facilities / Institutions: This can be circumvented at corporate level to some extent. It is suggested that the planning for this activity can start when companies plan to recruit trainees. Budgetary provisions and association with other incubation centers in a planned manner would minimize the adverse effect.

Change in Technology: adaptation can be achieved by corporate, quickly if they have the strategic **growth management department** as suggested above. HRM also should be done in a strategic manner for including succession and replacement planning.

Skill Inventories can be primarily generated, audited and validated at corporate level. It is suggested that at corporate level this activity be initiated. The results of the same should be shared with educational and training institutes, the nodal agencies and apex bodies of the government.

Finding Situational factors affecting Biotech HRP in India- related suggestions

High Supply of HR and High Demand for the same: (HSHD)

It was found that Computer Skills for administration, presentation
Etc. was in this HSHD situation for Indian biotech companies. For this the corporate can change entry level skill standard and proficiency level. With this change they can use the IT as a better tool and use it for automation of other processes, wherever possible. This will require specific skill level in handling process automation. This may be one way of balancing the situation.

Low Supply of HR and High Demand: (LSHD)

Scientist R and D are in low supply and are in high demand for biotech

companies. Initiatives by companies for becoming accredited research centers is necessary, for providing career path for scientists is suggested as a solution to this situation. Wockhardt is an example. This will provide a career path for development to postgraduates and scientists working in R and D.

Production technologists for commercialization, IPR, regulatory issues like OSHA, GMP, GLP experts etc. also are in short supply and high demand area. Patent registration and protection of IPR initiatives at corporate level will motivate people to take "these areas" as a career either in the company or with outside institutions. Industry institution cooperation for necessary education and training, with certification is another suggestion for overcoming difficulties arising out of this situation. The National Policy for Biotech has said volumes about it, so corporate level organization of companies can monitor and help policy makers convert the objectives into a reality into a realistic time frame.

High Supply and Low Demand:

Technical and non technical trainees are the section of population which has to face this situation in biotech companies. Organizations like ABLE may decide to have a co operative effort for handling these and other biotech HR issues. On the line of Biotech HR Canada (BHRC Canada), ABLE can start a new initiative, **Biotech HR India**. (ABLE has already suggested why not BIO India) This initiative, if taken at this level by corporate, it should get good support from DBT because it is going to serve part of the mission of DBT. Another measure at corporate level is to introduce aptitude tests. Starting with GMA- General Mental Ability test, which is one of the most useful tests for recruitment and selection also will provide valuable and useful filter.

Technical Skill sets required sector wise – Related Suggestion

This exercise of tracing the skill sets sector wise, by the researcher is an academic attempt to fill the gap of non availability of such information. At corporate level, a more systematic and on the basis of practical experience these lists can be again prepared, audited and validated. These will have to be kept open for addition or deletion as per changes in technology. All companies may make an attempt through organizations like ABLE for making a comprehensive

list base; designate appropriate skills for different sectors. Most important part of the skill sets database is, the process of their standardization and documentation of the same. It is suggested that the standardization process should include sector of application, background knowledge necessary to acquire the skill, specifications of processes carried out using skills (protocols) machines, instruments and other chemical and material resources required for operations to be carried out using the skill. This kind of data base will be useful to corporate for HRP and HRD purposes and also to training and development institutions.

Technical Skill Areas where it is Difficult to Source Trainers and Facilities- Related Suggestion

For the purpose of understanding the difficulty the areas are listed as responses of % of companies while critically analyzing the issue.

I. 100% of companies – DNA sequencing, DNA synthesis, Good Clinical Practices, Good Laboratory Practices, Cell/ Tissue culture, Bio Safety guidelines, QA/QC procedures, Good Manufacturing Practices, Sterile techniques, instrument validation, IPR related

II. 90% of companies – DNA isolation, RNA isolation, Immuno-Precipitation,

III 80% of companies – in vitro transcription, Recombinant DNA technologies, Imaging, Polymerase Chain Reaction, ELISA, Image Analysis

IV 75 % of companies – Southern blotting,

V 65 % of companies – Antibody production, Mutagenecity testing

VII 60 % of companies- In vitro mutagenesis, Hybridoma Techniques, Basic animal care

VIII 50% companies – Live animal handling,

IX 15 % of companies- Plant biotechnology techniques

As a matter of policy and infrastructure provision, this need is more addressed to the government apex bodies looking into the development of

biotechnology sector. However, companies do have the manpower and infrastructure, which they need to have for production purposes. The Association of Biotechnology Lead Enterprises can take a lead in providing necessary facilities. One such effort is being undertaken at Vidya Pratisthan,, Baramati, Maharashtra, where ABLE chief Dr. Kiran Mujumdar is participating as one of the chief mentor and trustee. Though the information from chief coordinator, Dr. Mrs. Chaphalkar indicates that, the center will provide these facilities and capabilities- being made ready for contract research and clinical trials- and for training and development also. Their focus area of operations would be agricultural biotechnology.

More ventures of this type catering to diverse needs, using the same skill sets are required. To sum it up, it can be said that there should be **"Polytechnic"** facility catering to the need of biotech sector and corporate can take the initiative. It could be a joint venture between state governments, chambers of commerce and corporate sector, keeping in mind the issues of feasibility, with backing by DBT.

Responses of companies – Difficult to Source Trainers with Biotech Orientation – Related Suggestion

Biotech orientation is in fact readily available with the companies. Companies can invite trainers and consultants who have interest and basic capabilities in specific skill training. Program for their biotech orientation may be developed by corporate sector and then there would be a batch of certified trainers with biotech orientation!

8.2.2 Educational Institutions

Growth in sales turnover of a company is positively related to growth in manpower. Educational institutions which cater to biotech sectors should make use of this finding for their own benefit as well as that of students and biotech companies.

It is easier for the institutions which provide management education. This is because they do have financial management as a subject and they can put students on practical project work and find out the relationship details. These

details are in terms of category of people who have affected the sales. This increase is going to create a demand for manpower from those biotech companies. The results from such projects would be useful for management as well as institutions catering biotech technical education. Educational institutions can correspond with the companies and establish the validity of their findings and decide their own action for providing the required number of people with necessary standard of education.

Estimation of HR Demand- Category wise Percentages

Education institutions catering to biotech companies requirements can make use of this information for structuring their courses and capacity of students for each course in a realistic way. They have to help students for placements in this competitive environment.

They do have placement cells and students work as coordinators. If the finding is used for generating category wise demand for biotech
Companies, then this data is useful for students to understand prospects and student counselors can advice and direct students while opting for specialization in the second year of the master degree courses. For a supplier, the demand trend is always useful parameter for preparing the products and services which he is supplying. In this context educational institutes may use this finding for their strategic framework.

Factors, Constraints Associated with HRP- related suggestion

Growth of Organization: It is suggested that educational institutions catering to needs of biotech companies should strive to match the infrastructure for education and training needs of the emerging needs. This requires long term strategic planning and institutions may develop alliances for this purpose with companies, for sustainable efforts.

Lack of Appropriate Training and Education Facilities / Institutions: Educational Institutions can take up a lead for enquiring with biotech corporate companies about the training and educational facilities they need and would need in future in a planned manner. This would facilitate planning and implementation. This is because, infrastructure for biotech education and

training is a multidisciplinary affair and right from location to building and class rooms, laboratories and appropriate facilities for research etc. take time and money. All this has to be done keeping in mind the evolving needs both technical and managerial. So long range projections would be helpful.

Lack of Data such as Skill Inventory: Educational institutes can design research projects for this type of need in collaboration with corporate. This will satisfy mutual need and inventories evolved through such research will be useful for all. This being more academic work having practical value, it is better done in collaboration. The present study has attempted to provide some data and methodology, which may prove to be niche!

Situational factors affecting Biotech HRP in India – Related Suggestion

High Supply of HR and High Demand for the same:

It was found that Computer Skills for administration, Presentation Etc. was in this situation for Indian biotech companies. For this the Educational institution can change their computer and IT related course structure and make more suitable to biotech, taking feedback at corporate level. With this change they can use the IT as a better tool and use it for automation of other processes, wherever possible. This will require specific skill level in handling process automation. With computer literacy, the advanced level courses only are going to attract students, as primary level skills now are acquired at school level.

Low Supply of HR and High Demand:

Scientist R and D are in low supply and are in high demand for biotech companies. Initiatives by educational institutions, for providing career path for scientists are suggested as a solution to this situation. Along with universities other colleges having master's degree program should create necessary research facility with university affiliation. This will provide a career path for development to postgraduates and scientists aspiring to work in biotech R and D.

Production technologists for commercialization, IPR, regulatory issues like OSHA, GMP, GLP experts etc. also are in low supply and high demand

area. Industry institution cooperation for necessary education and training, with certification is another suggestion for overcoming difficulties arising out of this situation. The National Policy for Biotech has said volumes about it, so educational institutes can monitor and help policy makers convert the objectives into a reality into a realistic time frame.

High Supply and Low Demand:

Technical and non technical trainees are the section of population which has to face this situation in biotech companies. Educational institutions now must take a review of their syllabi. Special efforts are required on the part of educational institutions to structure courses having real biotech component. For example biotech MBA should have enough content in botany, zoology, chemistry, microbiology, molecular biology, and latest technologies from management point of view. At Kellogg School of Management, United States, they call this as booting in biotechnology for management major students. All specialties like HR, finance, marketing can have biotech orientation. IPR, Regulatory affairs like GMP, GCP, and GLP are still not available as courses, and institutions can explore these areas as new horizons in the context of emerging biotech businesses.

Technical Skill sets Required sector wise – Related Suggestion

This exercise of tracing the skill sets sector wise, by the student is an academic attempt to fill the gap of non availability of such information. At Educational institutional level, a more systematic and on the basis of practical experience at laboratory level, these lists can be generated, audited and validated. These will have to be kept open for addition or deletion as per changes in technology. All institutions may make an attempt through organizations like UGC or CSIR for making a comprehensive list base, designate appropriate skills for different sectors. Most important part of the skill sets database is, the process of their standardization and documentation. It is suggested that the standardization process should include sector of application, background knowledge necessary to acquire the skill, specifications of processes carried out using skills (protocols) machines, instruments and other chemical and material

resources required for operations to be carried out using the skill. One can think of work books for acquiring these skills like there are books on experiments, with recipes. This kind of data base will be useful to corporate for HRP and HRD purposes at policy and implementation level.

Responses of companies – Difficult to Source Trainers with Biotech Orientation – Related Suggestion:

Educational institutions can develop a tie up with corporate for being a training provider and evolve courses for working managers from other domains for biotech orientation and Biotech specialists for orientation in other areas like regulatory affairs, ISO etc.

8.2.3 Other Institutions

Forecasting Demand for HR

Other institutions like National Chemical Laboratory, National Center for Cell Science, which are the research institutions for biosciences, can take a clue from the analysis of these findings. If the analysis shows that they have the capabilities to provide necessary scientific and technical training which would be necessary for the projected demand of the manpower, they can plan for the same. For this purpose they may have to develop a tie up with a management school or depute this work to some team in their own office. Obtaining sales figures for successive years is not a difficult task. When they are on the rise, the finding has provided a clue that the workforce demand is going to be there. They can make their own plans for supplying part of the demand within their scope of operations, provided it fits into their policy.

Estimation of HR Demand- Category wise Percentages

This estimation from biotech companies provides good directions for other institutions for setting objective for having joint programs of training and development. They can work in the area of R & D for initial research and production etc. Incubation centers and polytechnics can work for catering to technical skills.

Factors, Constraints Associated with HRP – Related Suggestions:

Other institutions being research institutions and incubation centers can provide interactive 'faculty ↔ company staff' exchange program. This will make the institutions aware about the problems of company, where they can extend assistance. Moreover the company staff can get to work with lab scale and be in learning mode for some time, which can build capabilities necessary for company.

Technical Skill sets Required sector wise – Related Suggestion

This exercise of tracing the skill sets sector wise, by the researcher is an academic attempt to fill the gap of non availability of such information. At other institutions level, for example National Center for Cell Sciences, National Chemical Laboratory, Institute of Bioinformatics, National Grape Research Institute, Vasant Dada Sugar Institute, CIMAP etc a more systematic and on the basis of practical experience these lists can be generated, audited and validated. These will have to be kept open for addition or deletion as per changes in technology. All institutions may make an attempt through organizations like NCCS for making a comprehensive list base; designate appropriate skills for different sectors. Most important part of the skill sets is, the process of their standardization and documentation of the same should begin. It is suggested that the standardization process should include sector of application, background knowledge necessary to acquire the skill, specifications of processes carried out using skills (protocols) machines, instruments and other chemical and material resources required for operations to be carried out using the skill. The institution may prepare audio visual material for training purposes. This kind of data base will be useful to corporate and apex bodies for HRP and HRD purposes.

8.2.4 Government (Apex bodies)

Forecasting Demand for HR – Related Suggestions:

Government apex bodies in biotechnology like the Department of Biotechnology, BCIL, HRD ministry, with easy access to authentic information, can use this for monitoring their strategic and operational force towards effectiveness for satisfying the emerging demand of workforce. These being

nodal agencies, they can issue directives to rest of the institutions and even biotech corporate sector for making a collaborative effort for continuous monitoring and improvement for satisfying the emerging demand of work force both in quantity and quality of industry standard.

Apex bodies like BCIL can compile this requirements state wise, region wise, and then for the whole country, for all categories of biotechnology companies. The Indian National Strategy for Development of Biotechnology has spelled out the requirement for the estimates of workforce requirement for biotechnology companies. This finding can be useful for apex bodies and they can collect this information company wise, sector wise etc. The results generated from the analysis of such data can be communicated to appropriate institutions by apex agencies. Apex agencies being policy makers and enablers can look into short comings of infrastructure and training and educational facilities necessary for satisfying the emerging demands.

Factors, Constraints Associated with HRP – Related Suggestions:

Apex bodies like DBT and BCIL from central government and biotech departments of respective state governments should have a joint programme for addressing the HR needs of Biotech corporate in India. BCIL has a directory published and there is a list of all the biotech companies and institutions who have subscribed. This has eliminated small companies for economic reasons or by the choice of the company due to the scale of operations. Even for registered companies, the mandates of BCIL, National Policy for Biotechnology-draft, do not have any concrete action plan. It is suggested that apex bodies can use a forum like CII or chambers of commerce and industries to form state wise biotech associations. For example, every state in united state has its own biotech association, where companies have membership. This kind of forum can provide avenues for co operative efforts for state of the art training and development facilities. MITCON has one incubation center, assisted by DST, in the sector of agricultural biotech. No such facility is available for bio Pharma. At present, Hindustan Antibiotics, the company under the control of government, is in a critical financial condition. The assets and infrastructure can be made use of for

bio Pharma training and development facility while still continuing its present antibiotic manufacturing. It will provide a very good incubation center (of course with addition of latest equipment capable of handling state of the art technology) for bio Pharma. Right from drug discovery, preclinical trials, clinical trials, etc to commercialization and marketing aspects of bio Pharma with regulatory norms can be covered. This can save the company; the people employed at present and will provide a profitable option for the enterprise. This will not only help the HRP aspect but can also provide services for HRD aspects.

Recruitment – Related Suggestions:

Indian Biotech Industry Needs and National biotechnology policy analysis reveals that "Reliable estimates of human resource availability for the next 10 years are required."

This is why at corporate level, supply sources are forecasted, without knowing the estimates of quantity and quality of candidates. Policy has spelled out a good framework of action plan for addressing this plan. For facilitating this in a smooth manner, apex bodies can provide a single window service and clearance for all the companies in biotech sector. The policy is still in draft stage and comments on DBT's biotech policy[1] are available at www.fbae.org, the website of The Foundation for Biotechnology Awareness and Education, Bangalore.

Proposed objectives by the policy are:

(i) National Task Force on Education & Training

(ii) Need Assessment

(iii) Curriculum Development

Dual degree programs in biotechnology that include regulatory matters, IPR and bio-enterprise management will be encouraged

(iv) Quality Improvement

(v) Strengthening of teaching and R&D in life sciences and Biotechnology in the university system

(vi) Attracting Talent to Life Science and Biotechnology

(vii) Creating science & technology leaders for the industry

(viii) Arresting and Reversing Brain Drain

(ix) Enabling working conditions for scientists to undertake industry oriented research, such as

a) *Lateral mobility of scientific personnel*

b) *Dual/adjunct faculty positions*

c) *Joint salary support*

d) *Rapid travel grants*

e) *Institute Innovation grants*

These steps will ensure that the large available resources of human talent in biotechnology are supported and this will guarantee the progress of the biotech sector.

It is suggested that DBT can take up inputs from agencies like Foundation for Biotechnology Awareness and Education and also invite suggestions and participation of competent people from academia and corporate. Competent people from corporate can be invited through ABLE. As they have better experience of all aspects of biotech business, if they decide to serve the community, they will be the best choice.

Situational Factors affecting Biotech HRP in India – Related Suggestions:

High supply of HR and High Demand for the same:

It was found that Computer Skills for administration, Presentation etc. was in this situation for Indian biotech companies. For this the corporate can change in entry level skill standard and proficiency level. With this change they can use the IT as a better tool and use it for automation of other processes, wherever possible. This will require specific skill level in handling process automation.

Low Supply of HR and High Demand:

Scientist R and D are in low supply and are in high demand for biotech companies. Production technologists for commercialization, IPR, regulatory issues like OSHA, GMP, GLP experts etc. also are in low supply and high demand area. Patent registration and protection of IPR initiatives at corporate level will motivate people to take this up as a career either in the company or with outside institutions. Industry institution cooperation for necessary education and training, with certification is a suggestion for overcoming difficulties arising out of this situation. The National Policy for Biotech has said volumes about it, so policy makers should convert the objectives into a reality into a realistic time frame.

High Supply and Low Demand:

Technical and non technical trainees are the section of population which has to face this situation in biotech companies. Organizations like BCIL may decide to have a co operative effort for handling these and other biotech HR issues. On the line of Biotech HR Canada, BCIL can have Biotech HR India. This initiative if taken at this level by BCIL, it should get good support from DBT because it is going to serve part of the mission of DBT. Another measure at BCIL level is to start initiatives for standardization of skills for biotech.

Technical Skill sets Required sector wise – Related Suggestions:

This exercise of tracing the skill sets sector wise, by the researcher is an academic attempt to fill the gap of non availability of such information. At Government apex body level, for example DBT, BCIL, DST, CSIR, UGC, ICAR etc a more systematic and on the basis of practical experience these lists can be audited and validated. These will have to be kept open for addition or deletion as per changes in technology. All bodies may make an attempt through organizations like BCIL for making a comprehensive list base; designate appropriate skills for different sectors. Most important part of the skill sets is, the process of their standardization and documentation of the same should begin. It is suggested that the standardization process should include sector of application, background knowledge necessary to acquire the skill, specifications

of processes carried out using skills (protocols) machines, instruments and other chemical and material resources required for operations to be carried out using the skill. This kind of data base will be useful to corporate and apex bodies for HRP and HRD purposes. A web based education initiative is also possible, for example Biotech Learning Institute[2] at San Jose, USA, has on line courses on many aspects of biotechnology and in their brochure the say "E-learning offers the most efficient and effective tool for training employees".

Technical Skill areas where it is Difficult to Source Trainers and Facilities – Related Suggestions:

For the purpose of understanding the difficulty the areas are listed as responses of % of companies while critically analyzing the issue.

I. 100% of companies – DNA sequencing, DNA synthesis, Good Clinical Practices, Good Laboratory Practices, Cell/ Tissue culture, Bio Safety guidelines, QA/QC procedures, Good Manufacturing Practices, Sterile techniques, instrument validation, IPR related

II. 90% of companies – DNA isolation, RNA isolation, Immuno-precipitation,

III 80% of companies – in vitro transcription, Recombinant DNA technologies, Imaging, Polymerase Chain Reaction, ELISA, Image Analysis

IV 75 % of companies – Southern blotting,

V 65 % of companies – Antibody production, Mutagenecity testing

VII 60 % of companies- In vitro mutagenesis, Hybridoma Techniques, Basic animal care

VIII 50% companies – Live animal handling,

IX 15 % of companies- Plant biotechnology techniques

As a matter of policy and infrastructure provision, this need is more addressed to the government apex bodies looking into the development of biotechnology sector. However, biotech companies do have the manpower and infrastructure for production purposes. The Association of Biotechnology Lead

Enterprises can be requested by BCIL for taking lead in providing necessary facilities. BCIL can take such initiative which will be coherent to the National Biotechnology Development Strategy- Draft. More ventures of this type catering to diverse need using the same skill sets are required to be developed like "Polytechnic" facility catering to the need of biotech sector and BCIL can take the initiative. It could be a joint venture between state governments, chambers of commerce and corporate sector, keeping in mind the issues of feasibility.

8.2.5 Trainers

Forecasting Demand for HR

Trainers: If the anticipated demand is going to be satisfied by effective use of training and development function, then trainer can make use of these findings. The trainer's community can find out the training need for the anticipated demand. If they have to structure new training activities in the light of new demand, then they can proactively plan those in co operation with the biotech companies. Individual trainers and training institutions, incubation centers can take this up as a clue and act accordingly.

Responses of Companies – Difficult to Source Trainers with Biotech Orientation

Trainers in all these domains can look at this a diversification opportunity. They can hone their skills of learning (as trainers are supposed to be perennial learners) to get orientation in biotech either with the help of institutions like National Cell Science Center, University Departments, or corporate sector senior level biotech managers.

8.2.6 Consultants

Forecasting Demand for HR

Recruitment consultants are especially interested in the demands of companies and this finding can be used by them for initiating actions from their end. They may co ordinate with the companies on the basis of -these findings and get details of emerging demand from the companies. In fact consultants can use this as an icebreaker and convert this into a workshop for people handling

HR in companies. This could be workshop for biotech HR planning and action plan for satisfying the demand which will emerge during the workshop. It could be a very practical workshop useful for biotech companies and consultants, both.

8.2.7 New Entrants and Trainees

Forecasting Demand for HR

New Entrants and Trainees: Students who are aspiring for job in biotech sector with their specialization in biotechnology, management, regulatory affairs, bio-safety etc can use this information for systematically studying about biotech companies. With this they can come to conclusion about which companies are going to need more workforce and they can prepare themselves accordingly. In preparation, they can improve their soft skills, but with the names of the companies they can study the profiles of the company for work culture, growth prospects etc.

8.3 Summary of findings and Conclusions

(A) General

(1) Modern biotechnology business originated with the founding of ‘Genentech’ on April 7, 1976 in the United States of America. Molecular basis of life and development in the related braches of science provide scientific basis for biotechnology and “Biotechnology” refers to the use of living organisms to develop products. Main applications of biotechnology use microbes and cell of living organisms while making useful products for improving plants & animals for better yield, disease resistance, for improvement of human health using bio pharmaceuticals and making many chemicals using bio processes for environmental & industrial purposes and improving quality of human life. Accordingly the biotech businesses have got organized into various sectors consisting of Bio Agricultural, Bio Industrial and Bio Pharma, etc.

The Bio-Pharma sector is leading globally and the extent of global spread of biotech business with revenue and employment generation is illustrated using the comparison of employment generation, net income and R and D spending in biotech in different regions, etc. as follows:

	Employment Numbers				
Year	**Global**	**US**	**Europe**	**Canada**	**Asia Pacific***
2002	188703	141000	34180	7005	6518
2004	183820	137400	25640	7370	13410

*Asia Pacific is comprised of **China, India, Korea Japan, Korea, Malaysia, Singapore and Taiwan.**

US $ million **FY 2002**	**Global**	**US**	**Europe**	**Canada**	**Asia Pacific***
Net income	5304	4317	484	408	94
R & D Spending	20888	15701	4151	782	253

*Asia Pacific is comprised of **China, India, Korea Japan, Korea, Malaysia, Singapore and Taiwan.**

The region wise employment generated in 2002 and 2004 gives clear idea about the employment capacity in this business. It is highest in the US and lowest in the Asia Pacific region, as the business there is in an emerging stage.

(2) The biotech operations start with R and D organization and then grow through the stages of manufacturing and distribution organization. As the process moves from laboratory to manufacturing plant, the type of workforce changes and size of the workforce grows. At early stages, people with graduates degrees in science are required, when manufacturing begins, more people with only a high school diploma or college education are required. The main departments’ created and operational stages in biotech organization are:

(i) Research and Development:

(ii) Pilot Scale Manufacturing

(iii) Clinical Trials and New Drug Application Process

(iv) Scaling up to Commercial Production

(v) Large-Scale Manufacturing

Job functions which specify tasks for biotech operations for manufacturing are:

Care for Research Animals/Plants, Communicate and Document Information (written, Oral, Electronic), Perform Initial Research, Comply with current Accreditation and Government Regulations, Maintain Quality Assurance, Control Inventory, Evaluate, Document and Report Results, Maintain Equipment and Facility, Maintain Professional Competency, Manufacture Products, Observe and Document Safe Practices, Obtain Specimen of Materials, Perform Tests /Assays, Process Materials.

(B) Job Positions & Knowledge and Skill Sets Required in Biotech Business: People are the only element with the inherent power to generate value. This seemed to be true in case of biotech businesses. The HRM functions were seen to be technology specific. In order to understand job positions available in biotech businesses, an extensive study of job descriptions and job specifications was carried out. An inventory of job positions almost common in biotech business organizations is as given below:

Area/Department	Job Positions
Research and Development	Glass washer, Greenhouse Assistant, Laboratory Assistant, Media Prep Technician, Plant Breeder, Research Assistant, Postdoctoral Fellow, Research Associate.
Quality Control	Environmental Health and Safety Specialist, Quality Assurance Auditor, Quality Control Analyst, Quality Control Engineer, Validation Engineer, Validation Technician.
Clinical Research	Animal Handler, Animal Technician, Biostatistician, Clinical Coordinator, Clinical Data Specialist, Clinical Programmer, Clinical Research Administrator, Clinical Research Associate, Drug Experience Coordinator, Technical Writer.
Manufacturing & Production	Assay Analyst, Biochemical Development Engineer, Instrument Calibration Technician, Manufacturing Engineer, Manufacturing Research Associate, Manufacturing Technician, Packaging Operator, Process Development Associate, Product Development Engineer, Production Planner Scheduler.

Regulatory Affairs	Documentation Coordinator, Documentation Specialist, Regulatory Affairs Specialist.
Information Systems	Library Assistant, Scientific Programmer Analyst
Marketing and Sales	Customer Service Representative, Market Research Analyst, Sales Representative, Systems Analyst, Technical Services Representative.
Administration	Buyer, Human Resources Representative, Patent Administrator, Patent Agent, Technical Recruiter.

A further analysis of job specifications and job descriptions coupled with review of recruitment and selection process led to understanding of knowledge and skill sets required. Accordingly, biotech HR required general knowledge base with a strong grounding in subjects like Biology, Chemistry, Mathematics, Engineering etc and diverse computer skills. The Industrial knowledge and skill sets found to be essential for biotech career can be listed below:

Analytical Instrumentation, Basic laboratory work, General Process Operations, Instrumentation and process control, Maintenance and Engineering, Other analytical/laboratory methods, Pharmaceutical Manufacturing technology, Process Development/Optimization, Regulatory compliance, Unit Operations.

The skills such as Business/ technical writing and communication, Business economics, Organizational psychology, Teamwork principles /practices, Supervisory skills, Project management are also required.

C) Demand for HR

The biotech work force composition as estimated from data for three years 2000-01, 2001-02 and 2002-03 shows following characteristics of biotech workforce demand composition

1. Maximum number of employees is that of Graduates and

   Post Graduates (about 57 %)

2. Second in ranking is that of B. Tech /MBA (27%)
3. Third category in rank is M.Tech./M.phil 6 to 9%
4. Next in the line is others 4-6 %

5. Least % is Ph. D. 3- 5%

The Demand for Human resources when analyzed for selected companies provided:

i) In the case of each company the number of manpower or

Workforce employed is on the increase.

j) The increase is substantial and corresponding increase in sales figure is also seen.

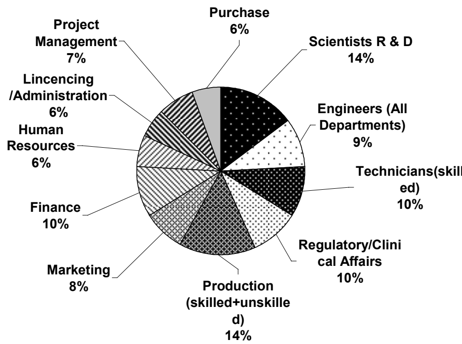
Further analysis of Demand for HR of different categories:

- For all companies there are unfilled positions in one category or other.
- The maximum unfilled positions are for following categories.
    a) Production, Scientist R and D
- Reason behind unfilled position is lack of qualified candidates, which is no availability of them.
- By and large the companies do not think that "compensation expected by qualified candidates is too high" is the reason for the positions remaining unfilled.

Following Technical Skills sets are Found to be Required:

Antibody Production, Basic Animal Care, Bio-Safety Guidelines, Cell Culture, Column Chromatography, Database, DNA Isolation, 8.DNA Sequencing, DNA Synthesis, ELISA, Gel Electrophoresis, Good Clinical Practices(GCP), Good Laboratory Practices (GLP), Good Manufacturing Practices(GMP), Groupware/IT, High Pressure Liquid Chromatography (HPLC), Hybridoma Techniques, Immuno-Precipitation, In Vitro Mutagenesis, In Vitro Transcription, In Vitro Translation, Instrument Validation, IPR Related, Live Animal Handling, Mutagenecity Testing, Polymerase Chain Reaction(PCR), Peptide Synthesis, Protein Purification, QA/QC Procedures, Recombinant DNA Technologies, RNA Isolation, Southern Blotting, Sterile Technique, Bioinformatics, Image Analysis, Imaging, Spreadsheet, Word Processing, Presentation, Graphics

Estimation of Demand for HR for all categories was found to be as follows:



(D) Supply of HR

An extensive study of recruitment mechanism further provided information about the supply sources for biotechnology companies. It was found that the sources and methods of recruitment for biotech businesses are similar to those generally used by other businesses.

Internal Sources: In the form of job content change, promotion, transfer etc. provides necessary HR from internal manpower available with the company. Training and development, organizational development and change management initiatives are practiced by companies while making use of internal sources of HR.

Management Skills and Competencies needs found as training requirements for development of internal source are: Conceptual Skills, Effectiveness Skills, Interpersonal Skill, Communication Skills, and Management Skill Development for Scientists, Better understanding of Science, Technology, Business Operations and Strategic issues for Managers, and Training for Processes such as GMP, GLP, OSHA etc.

Similarly **Skills Related to Specific Function-Training needs are found to be** Bio-Safety, Customer Relationship, Finance- Business Economics, Human Resources Planning, Human Resources Training and Development,

Licensing / Administration, Marketing, Production, Regulatory affairs, Research and Development, Third Party Certification e.g. ISO.

External Sources: Educational institutions, recruitment consultants and advertisements through different media for example print media and electronic media etc. provide HR from external sources.

(E) Factors influencing HRP & D processes and practices:

1. Training and Education facilities /Institutions: The analysis of this factor suggests that the education and training facilities pertaining to biotech industry are scares and there is a need to develop them keeping in mind the demand of HR by this industry.

Areas where it is Difficult to Source Technical Training from Outside the Company with % of companies facing that problem:

100% of Companies – Bio Safety Guidelines, Cell/ Tissue Culture, DNA Sequencing, DNA Synthesis, Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices, Instrument Validation, IPR Related, QA/QC Procedures, Sterile Techniques.

90% of Companies – DNA Isolation, Immuno Precipitation, RNA Isolation,

80% of Companies – ELISA, Image Analysis, Imaging, Polymerase Chain Reaction, In Vitro Transcription, Recombinant DNA Technologies,

75 % of Companies – Southern Blotting,

65 % of Companies – Antibody Production, Mutagenecity Testing

60 % of Companies- Basic Animal Care, Hybridoma Techniques,

In Vitro Mutagenesis,

The following areas were found where it was Difficult to Source Trainers with Biotech Orientation: Bio-Safety, Customer Relationship, Ethics, Human Resources Planning, Human Resources Training and Development, Regulatory Affairs, Licensing / Administration.

2. **Information and Data about Skill Sets and Competencies:** is not available as a set of information characteristic to the biotech business operations. The information about technical, managerial, regulatory skill sets need to be systematically developed for all sectors of biotech business.

3. Business Policies followed by Biotech Companies: The policy of local or global competition, diversification, mergers and acquisitions, and business model for operational purposes affect to a great extent the HRP & D activities.

4. Role of HR Management was found to be as a supportive function and integration of HR function with strategic management function was to the extent of maintenance part of HR function.

5. Retention or Replacement Planning: As the biotech business is in infant stage and in the light of non availability of candidates with necessary knowledge and skills, replacement planning is not feasible and retention measures, like educational benefits, OD are practiced.

6. Compensation and Welfare Practices: The salaries have increasing trend as was observed for the period 2002-03 and 2003-04 and welfare and compensation practices are found to be considerable.

Conclusions

(1) The biotechnology businesses are peculiar in terms of resources, products, business operations and organization. Raw materials used are live plant and animal cells and microorganisms. This makes the processes more knowledge and research oriented and human resources with specific knowledge and skills so as to handle these bio processes are required. Work force requirement of biotech business is that of ‘high skill’ workforce. Products obtained from natural or modified life processes of live organisms, plant and animal cells are in form of different useful chemicals, genetically modified organisms or plants, seeds etc. Peculiarity of modern biotech products is that they can be designed using modern biotechnology for obtaining predictable results. They affect almost all areas of human existence from birth to death. They also are effective in

modifying the human environment both natural and manmade. Biotech business operations are technology driven. They typically begin with R and D activity and the knowledge and skills required are highly specialized. The commercialization of biotech products involves proprietary rights issues and many regulatory issues both local and global. The bio safety and bio ethics issues are peculiar to this business; intellectual property right of the innovation provides protection to these operations to some extent in global commercial scenario. Biotech business operations both technical and managerial require strong orientation of technology for effective performance. Organization of biotech business starts with an innovation and the scientists who invent the new product or process becomes an entrepreneur in most of the cases. The organization is thus influenced more by techno structure than operating core. It could be an R and D organization, Manufacturing organization, Sales and Distribution organization or a combination of any two or all three. They may also function as Contract Research Company, Contract Manufacturing Company, Contract Sales & Marketing Company etc.

(2) This industry requires highly knowledgeable workforce with skills and capabilities of handling technical operations at molecular biology level and at still smaller (Nano biotechnology) level for harnessing the technology for making useful products and services. It has become a global phenomenon and biotechnology is fast growing industrial sector. Education, training necessary for preparation of workforce with right type of skills and competencies needs infrastructure which is scares. The time and cost requirement of education and training is enormous, as the technology is emerging and the nodal agencies are in the stage of development. The skill set requirement is bimodal, both technical R & D and Managerial. All these have resulted into non availability of right type of workforce for this industry.

(3) In the case of almost all biotech companies the number of manpower or workforce employed is on the increase. The range of increase during 2002-03 & 2003-04 is from 12% to 115 %. The percentage estimation of HR demand for each category in relation to total HR is found to be : The maximum percentage is that for two categories: R and D (14%) and Production (14%),

Regulatory/clinical, Technicians, Finance (10%), Then Engineers 9%, Project Management 7% and Purchase, Licensing/Administration and Human Resources are 6 % each.

(**4)** HR supply situation of biotech workforce seemed to be characterized by Lack of educational facilities of appropriate standards, Academic Taboos such as is biotechnology an applied science? is it engineering and technology? Is the person working a scientist, manager, engineer or a laboratory technician? and so on.

Moreover, scale of operations also demands different compositions of workforce skills and competencies.

(5) The HR planning and Development processes are complex and subject to rapid changes because of advent in technology in different areas of biotech such as tissue culture, healthcare, monoclonal antibodies, industrial and environmental. They fall into broad categories viz. Agriculture, Bio Pharma, and Industrial etc., as described earlier. The manpower requirements and related issues are not yet very satisfactorily addressed because of lack of information and experimental phase of the business. As a result:

- There is a shortfall of qualified manpower, which is a particular problem of this sector.
- The impact of globalization and competitive environment have taught industry to understand the importance of evolving and following good HR practices for retaining the workforce.
- There is a need for creation of awareness and facilities for developing human resource from the viewpoint of technical as well as managerial capabilities and skill sets necessary for biotech sector.

People are the only element with the inherent power to generate value. All the other variables offer nothing but inert potential. By their nature they add nothing, and they cannot add anything until some human being leverages that potential by putting it into play. This has following imperatives:

- Potential of the technology for value addition can only be harnessed by people with necessary education, skills and competencies.
- This creates a demand that top management attract, cultivate and retain the best workforce they can possibly find.
- This makes the role of human resource managers as important if not more, as any other executive leadership function.

Appendix I: Questionnaire

"A Study of Human Resource Planning and Development in Biotech Businesses"

Name of the Researcher: Prakash Deshpande
Name of the Guide: Dr. S.V. Kadvekar Director,
Research Guide, Pune University,
Faculty of Management.
Research Center: Department of Management Sciences. University of Pune.

Questionnaire

Please provide the following information before filling in further details.

Company name:
Address:
Tel:
Web site:
Establishment Year: (G-01)
Biotech Sector/ category: (G-02)

Organization Chart: Please provide your organization chart.

Pl. use a separate sheet if necessary.

FORECASTING

Q. 1. No. of people employed in your organization for these 2 years 2002-03 [ ] and 2003-04 [ ]

Q2 B Are there **unfilled** biotechnology related positions in your unit?
O No Yes go to question (2C)
Q2C → **fill in the following information and Tick Reasons for the same**

Position /Category	**No. of unfilled Positions**	**Lack of qualified Candidates**	**Compensation Expected by Qualified candidates too High**
Scientists R and D			
Engineers (all departments)			
Technicians (skilled)			
Regulatory /clinical affairs			
Production (skilled + Unskilled)			
Marketing			
Finance			
Human Resources			
Licensing / Administration			
Project Management			
Purchase			
Total			

Q.3 Please give the percentage of technical and non technical trainees.

1. Technical trainees %

2. Non technical trainees %

Q.4 Please describe HR planning process in your company.

RECRUITING

Q5 Recruitment Practices					
Tick mark the applicable methods used to fill the positions, in boxes provided					
Always=1, Often=2, Some Times=3, Rarely=4 Never= 5	**Frequency of use**				
	1	**2**	**3**	**4**	**5**
Internet resources					
University/Campus Recruitment					
Recruit Trainees					
Temporary/contract staff					
Employment agencies/Consultants					
In house training					
Recommendations, Personal contacts					
Newspapers/Journal advertisement.					
Professional Associations					
Collaborate with institutions					
Any other (please specify)					

- Please give information about recruitment process followed by You. For Example: Advertisement-Resumes-short listing-testing-Group Discussion, Personal Interview-etc. Please describe in brief.
- Your comments on Entry level, technical and Managerial Positions.
- Your comment on sources used for different categories of employees

  (Please use separate sheets where necessary)

RETENTION

Q.6 What are the workforce welfare practices followed by your Organization? Please write N. A. if not applicable			
	Welfare measure	**YES**	**N. A.**
1	Subsidized food at unit canteen		
2	Recreation facility at unit		
3	Health club at unit		
4	Subsidized transport facility, home to unit		
5	Family welfare schemes		
6	Medical Insurance		

	Educational Benefits		
7	Complete tuition fee reimbursement		
8	Partial tuition reimbursement Pl. specify %		
9	Reimbursement for workshops		
10	Complete paid leave/sabbatical		
11	Any other (please specify)		

Q. 7 Do you follow any performance appraisal system, for example 360-degree appraisal? or Assessment center? Please state in brief.

Q. 8 Do you follow the practice of succession planning in your 0rganization? Please state in brief.

II. Identifying Job Skill and Competency

Q. 9 a) Please tick mark the technical job skill and competency areas applicable to your company.

	Skill and Competency	Y		Skill and Competency	Y
01	DNA Sequencing		21	Sterile Technique	
02	DNA Synthesis		22	HPLC	
03	Gel Electrophoresis		23	Protein Purification	
04	Column Chromatography		24	*In vitro* translation	
05	Good Laboratory Practices (GLP)		25	*In vitro* mutagenesis (site directed)	
06	Good Clinical Practices (GCP)		26	Hybridoma techniques	
07	Cell / Tissue culture		27	Antibody production	
08	DNA isolation		28	Instrument validation	
09	RNA isolation		29	Bioinformatics	
10	*In vitro* transcription		30	Image analysis	
11	Recombinant DNA technologies		31	Basic animal care	
12	Live animal handling		32	Plant biotechnology technique	
13	Bio-safety guidelines		33	IPR related	
14	QA / QC procedures		34	Mutagenecity testing	
15	Imaging		35	Peptide synthesis	
16	Southern blotting		36	*Word processing*	
17	P Chain Reaction (PCR)		37	*Spreadsheet*	
18	ELISA		38	*Database*	
19	Immuno-precipitation		39	*Presentation, graphics*	
20	Good Manufacturing Practices (GMP)		40	*Groupware, IT*	

Q. 10 which are the areas for which you have difficulty in sourcing the trainers ? Please tick against the applicable areas.

	Skill and Competency	Y		Skill and Competency	Y
01	DNA Sequencing		21	Sterile Technique	
02	DNA Synthesis		22	HPLC	
03	Gel Electrophoresis		23	Protein Purification	
04	Column Chromatography		24	*In vitro* translation	
05	Good Laboratory Practices (GLP)		25	*In vitro* mutagenesis (site directed)	
06	Good Clinical Practices (GCP)		26	Hybridoma techniques	
07	Cell / Tissue culture		27	Antibody production	
08	DNA isolation		28	Instrument validation	
09	RNA isolation		29	Bioinformatics	
10	*In vitro* transcription		30	Image analysis	
11	Recombinant DNA technologies		31	Basic animal care	
12	Live animal handling		32	Plant biotechnology technique	

13	Bio-safety guidelines		33	IPR related	
14	QA / QC procedures		34	Mutagenecity testing	
15	Imaging		35	Peptide synthesis	
16	Southern blotting		36	*Word processing*	
17	P Chain Reaction (PCR)		37	*Spreadsheet*	
18	ELISA		38	*Database*	
19	Immuno-precipitation		39	*Presentation, graphics*	
20	Good Manufacturing Practices (GMP)		40	*Groupware, IT*	

Q. 11.Identifying Managerial Skills and competency and

a) Training Need assessment for Entry Level candidates Please tick mark in appropriate box

Conceptual Skills	**High**	**Med**	**Low**
1.Ability to use information to solve business Problems			
2.Identification of opportunities for innovation			
3.Recognizing problem areas and implementing Solutions			
4.Selecting critical information from masses of Data			
5.Understanding of business usage of Technology			
6.Understanding of Organization's business Model			

Effectiveness skills	**High**	**Med**	**Low**
1.Contribution to Corporate mission/Department objective			
2.Customer focus			
3. Multitasking, working at multiple tasks in parallel.			
4. Negotiation Skills			
5.Project Management Skills			
6.Reviewing operations and implementing Improvements			
7. Setting and maintaining performance standards			
8. Internal : Self and subordinate activities			
9. External: vendors, suppliers, business			
10. Setting priorities for attention and			
11. Time Management			

Interpersonal Skills	**High**	**Med**	**Low**
1.Coaching and mentoring skills			
2.Diversity skills: Working with diverse people And Cultures.			
3. Networking within the organization.			
4. Networking outside the organization.			
5.working in teams (cooperation and commitment)			

	Communication Skills	**High**	**Med**	**Low**
1.Credibility among colleagues, peers and Subordinates				
2.Ability to transform ideas into words and actions				
3.Listening and asking questions				
4.Presentation skills, spoken formats				
5.Presentation skills, written / Graphic format				

Q. 12.Tick mark the requirement of the need for extensive training for entry level candidates to suit the biotech business.

Specific Function Skill	Training need entry level			
A=Always, O=Often S=Sometimes, R=Rarely	A	O	S	R
Marketing				
Human Resources Planning				
Human Resources Training and Development				
Finance, Business Economics				
Customer relationship				
Bio-safety				
Regulatory affairs				
Licensing / Administration				
Production				
Ethics				
Third Party Certification e.g. ISO				
Research and Development				

Leadership Development

Q. 13. Do you foster leadership development by designating high-potential employees, Coaching, Mentoring, and Rotating People into Different Projects?

Yes – Always(1), Often(2) Sometimes(3), Rarely(4) , No -- never(5)

Q14. Please tick mark areas for which it is difficult to source trainers, with biotech orientation.

Specific Function Skills	**Difficult to Source Trainers**
	Y
Marketing	
Human Resources Planning	
Human Resources Training and Development	
Finance, Business Economics	
Customer relationship	

Bio-safety	
Regulatory affairs	
Licensing / Administration	
Production	
Ethics	
Third Party Certification e.g. ISO	
Research and Development	

Q15 What are the constraints for not providing training even if the need was there?

Shortage of venue	
Lack of information providers	
Non-availability of employee time	
Finance Policies	
Lack of suitable courses	
Loss of time from work	
Lack of employee policy	

Q16 What are most important needs of Indian Biotech Human resource?

I	What are the most important HR needs at present	Please tick mark for "yes"
1	Organizational Development	
2	Management Skill Development, for scientists	
3	Better understanding of Science, Technology, business	
4	Standardization processes like ISO, GMP, GLP etc.	
5	Improvement in compensation and welfare measures.	
6	More facilities for Learning	

Q17. Financial details (HR related) of the company

Q 17	Please provide the financial details in the following table for financial years and in lakhs of rupees. In figure or 2.As a percentage to sales						
		Financial Year					
	A=Actual B=Budgeted	**2001-02**		**2002-03**		**2003-04**	
		A	**B**	**A**	**B**	**A**	**B**
	Total sales /Revenue						
	Biotech sales						
	Total Budget for HR department						
	Actual spending of HR department						
	Appropriation of the budget						
01	Salaries						
02	Allowances						
03	Perquisites						
04	Fringe benefits						
05	Bonus						
06	Gratuity						
07	Cash rewards						
08	Training expenses (Technical)						
09	Training expenses (Managerial)						
10	Education						
11	Seminars, workshops etc.						

12	Entertainment						
13	Welfare (statutory)						
14	Welfare (non statutory)						
15	Other (please specify)						

Q18. Your views and comments about any other aspects of HR Planning and Development for Biotechnology businesses

Your Views and Comments
If you have any comments about some points mentioned below and any other points, Please give them in the space below. Use separate sheets if required
1. Central /State Government Biotech Policy
2. Standardization and Certification of biotech technical skills, and special managerial skills related to Biotechnology in India
3. Factors affecting workforce/manpower planning
4. Opinion on the quality and extent of biotech education available in India.
5. Opinion about biotech training and skill development facilities and expertise available in India.
6. Any other pertaining to Biotech HR planning and development, workforce turnover, retention, succession, special HR practices etc.
Thank You for your time and valuable cooperation. **Please return the questionnaire to the researcher, in a separate envelope. Or** **Email if you prefer filling in Soft-copy to** **deshpandep@unipune.ernet.in prakashdeep@gmail.com**

Appendix II: List of Biotech Companies Studied

1	**Biocon Ltd.** 20th KM Hosur Road ,Electronics City,Bangalore 560 100. India. Ph: 91 80 2808 2808, Fax: 91 80 2852 3423. http://www.biocon.com email: contact.us@biocon.com
2	**Serum Institute of India Ltd.** 212/2, Hadapsar, Off Soli Poonawalla Road,Pune-411042. India. Ph.+91-20-26993900. Fax+91-20-26993921 http://www.seruminstitute.com/ Email:contact@seruminstitute.com
3	**Pancea Biotec Ltd.** B-1 Extn. / A-27, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi- 110044, India. Phone : +91-11- 51678000, 51679000, Fax : +91-11-51044550. http://www.panacea-biotec.com/ Email : corporate@pblintranet.com
4	**Nicholas Piramal India Ltd.** Nicholas Piramal Tower,Ganpatrao Kadam Marg,Lower Parel, Mumbai 400 013 Tel- 91-22-56636666 (board nos) Fax: 91-22-24172851 (board numbers) http://www.nicholaspiramal.com/ Email- customercare@nicholaspiramal.co.in
5	**Novo Nordisk (I) Pvt. Ltd.** 8th Floor, Raheja Towers, East Wing, 26/27, M.G. Road, Bangalore 560 001 India. Tel: +91-80-25327447, Fax : +91-80-25594409 Email: india@novonordisk.com http://www.novonordisk.co.in/documents/home_page/document/index.asp
6	**Venkateshawara Hatcheries Pvt.Ltd.** 17/6, Milestone, Pune Panshet Road, Post Office Girinagar, Pune 411025. Phone : (020) 24389471, 24389474 Tele Fax : (020) 24389471 http://www.venkys.com/ http://www.ventribio.com/index-ie.html
7	**Wockhardt Ltd.** Wockhardt Towers Bandra Kurla Complex, Bandra (East),Mumbai 400 051, India. Tel: 91-22-2653 4444 Fax: 91-22-2653 4242 http://www.wockhardt.com/ Email: ocassubhoy@wockhardtin.com
8	**GlaxoSmithKline Pharmaceuticals Ltd.** Dr. Annie Besant Road, Worli, Mumbai - 400 030. Tel: +91 22 2495 9595, Fax: +91 22 2495 9494. http://www.gsk-india.com/index.asp Email: askus@gsk.com
9	**Bharat Serums & Vaccines Ltd.** Hoechst House, 16th Floor, Nariman Point, Mumbai – 400021. Maharashtra, India. Tel.: 91-22-56560900 Fax. : 91-22-56560901 http://www.bharatserums.com E-mail : corporate@bharatserums.com
10	**Eli Lilly and Company (India) pvt. Ltd.** Plot # 92, Sector 32, Institutional Area, Gurgaon-122001.HARYANA, INDIA. Phone : 91-124-2823000,01 Fax : 91-124-2823012, 13 http://www.lilly.com, http://www.lillyindia.co.in/ Email : lillyindia@lilly.com

11	**Novozymes South Asia Private Limited** No. 16, 7th Floor, Innovator, International Technology Park, Whitefield Road Bangalore 560 066. India. Tel. +91 80 28418275/ 28418280/ 28418285 Fax +91 80 28410451 / Telex 2845 8610. http://www.novozymes.com/ Email: N.A. contact through website
12	**Quintiles Spectral (India) Private Ltd.** 712, Midas, Sahar Plaza, Mathurdas Vasanji Road, Andheri (E).Mumbai, 400059. India Tel: +91 22 2820 1003. Fax: +91 22 2820 0485 http://www.quintiles.com/default.htm
13	**Krebs Biochemicals & Industries Ltd.** #401/402, 4th Floor, Cyber Heights, Plot No 13, Road No 2, Banjara Hills, Hyderabad – 500033. Andhra Pradesh. India. Phones: +91-040-23540415 / 55593678 / 55594798 Fax: +91-040-23540320 http://www.krebsbiochem.com/ E-mail: mail@krebsbiochem.com
14	**Indian Immunologicals Limited** Indian Immunologicals Ltd. Road no 44, Jubilee Hills, Hyderabad-33. Tel: 91-40-55512425, Fax: 91-40-23544007 http://www.indimmune.com/
15	**Zydus Cadila(Cadila Healthcare Ltd.)** Zydus Tower, Satellite Cross Roads, Ahmedabad 380015. India Tel: 91-79-26868100 Fax: 91-79-26862366 http://www.zyduscadila.com/homepage/ Email: knowzydus@dialforhealth.net
16	**Maharashtra Hybrid Seed Company (Mahyco)** **Mahyco Research Center** P. O. Box - 76, Aurangabad - Jalna Road, At post Dawalwadi, Dist. Jalna. Tel No. : +91 2482 236830, 236838, 262001-01 Fax : +91 2482 234621 http://www.mahyco.com/ Email :info@mahyco.com
17	**Shantha Biotechnics** 3rd Floor, Serene Chambers, Road No.7, Banjara Hills, Hyderabad - 500 034 INDIA. Phone: +91-40-23543010, 23548507, 23608843 Fax: +91-40-23548476 http://www.shanthabiotech.com/ E-mail: info@shanthabiotech.com
18	**Syngene Internationals** 20th KM Hosur Road, Electronics City , Bangalore 560 100. India Tel 91 80 2808 2808/ 2783 2169. F 91 80 2852 3423/ 2783 1070 http://www.biocon.com/syngene.asp
19	**Biological E Ltd.** 18/1&3, Azamabad, Hyderabad - 500 020, A.P., India. Tel: 91-040-27617831, 27617835, 27615134 Fax: 91-40-27615309, 27616715, 27630307 http://www.biologicale.com info@biologicale.com
20	**Span Diagnostics Ltd.** 173-B, New Industrial Estate, Udhna, Surat - 394 210, INDIA. Phone :-261-227 7211, 227 7143, 227 9583, 227 4528. Fax : +91-261-227 9319 http://www.span.co.in Email:espanol@span.co.in

Appendix III: Time Line- Biotechnology

8000 B.C.

Humans domesticate crops and livestock.

Potatoes first cultivated for food.

4000–2000 B.C.

Biotechnology first used to leaven bread and ferment beer, using yeast (Egypt).

Production of cheese and fermentation of wine (Sumeria, China and Egypt).

Babylonians control date palm breeding by selectively pollinating female trees with pollen from certain male trees.

500 B.C.

First antibiotic: moldy soybean curds used to treat boils (China).

A.D. 100

First insecticide: powdered chrysanthemums (China).

1322

An Arab chieftain first uses artificial insemination to produce superior horses.

1590

Janssen invents the microscope.

1663

Hooke discovers existence of the cell.

1675

Leeuwenhoek discovers bacteria.

1761

Koelreuter reports successful crossbreeding of crop plants in different species.

1797

Jenner inoculates a child with a viral vaccine to protect him from smallpox.

1830–1833

1830—Proteins discovered.

1833—First enzyme discovered and isolated.

1835–1855

Schneider and Schwann propose that all organisms are composed of cells, and Virchow declares, "Every cell arises from a cell."

1857

Pasteur proposes microbes cause fermentation.

1859

Charles Darwin publishes the theory of evolution by natural selection. The concept of carefully selecting parents and culling the variable progeny greatly influences plant and animal breeders in the late 1800s despite their ignorance of genetics.

1865

Science of genetics begins: Austrian monk Gregor Mendel studies garden peas and discovers that genetic traits are passed from parents to offspring in a predictable way—the laws of heredity.

1870–1890

Using Darwin's theory, plant breeders crossbreed cotton, developing hundreds of varieties with superior qualities.

Farmers first inoculate fields with nitrogen-fixing bacteria to improve yields.

William James Beal produces first experimental corn hybrid in the laboratory.

1877—A technique for staining and identifying bacteria is developed by Koch.

1878—The first centrifuge is developed by Laval.

1879—Fleming discovers chromatin, the rod-like structures inside the cell nucleus that later came to be called chromosomes.

1900

Drosophila (fruit flies) used in early studies of genes.

1902

The term ***immunology*** first appears.

1906

The term ***genetics*** is introduced.

1911

The first cancer-causing virus is discovered by Rous.

1914

Bacteria are used to treat sewage for the first time in Manchester, England.

1915

Phages, or bacterial viruses, are discovered.

1919

First use of the word ***biotechnology*** in print.

1920

The human growth hormone is discovered by Evans and Long.

1928

Penicillin discovered as an antibiotic: Alexander Fleming.

A small-scale test of formulated *Bacillus thuringiensis* (Bt) for corn borer control begins in Europe. Commercial production of this biopesticide begins in France in 1938.

Karpechenko crosses radishes and cabbages, creating fertile offspring between plants in different genera.

Laibach first uses embryo rescue to obtain hybrids from wide crosses in crop plants—known today as hybridization.

1930

U.S. Congress passes the Plant Patent Act, enabling the products of plant breeding to be patented.

1933

Hybrid corn, developed by Henry Wallace in the 1920s, is commercialized. Growing hybrid corn eliminates the option of saving seeds. The remarkable yields outweigh the increased costs of annual seed purchases, and by 1945, hybrid corn accounts for 78 percent of U.S.-grown corn.

1938

The term ***molecular biology*** is coined.

1941

The term ***genetic engineering*** is first used, by Danish microbiologist A. Jost in a lecture on reproduction in yeast at the technical institute in Lwow, Poland.

1942

The electron microscope is used to identify and characterize a bacteriophage—a virus that infects bacteria.

Penicillin mass-produced in microbes.

1944

DNA is proven to carry genetic information—Avery et al.

Waksman isolates streptomycin, an effective antibiotic for tuberculosis.

1946

Discovery that genetic material from different viruses can be combined to form a new type of virus, an example of genetic recombination.

Recognizing the threat posed by loss of genetic diversity, the U.S. Congress provides funds for systematic and extensive plant collection, preservation and introduction.

1947

McClintock discovers transposable elements, or "jumping genes," in corn.

1949

Pauling shows that sickle cell anemia is a "molecular disease" resulting from a mutation in the protein molecule hemoglobin.

1951

Artificial insemination of livestock using frozen semen accomplished.

1953

The scientific journal *Nature* publishes James Watson and Francis Crick's manuscript describing the double helical structure of DNA, which marks the beginning of the modern era of genetics.

1955

An enzyme involved in the synthesis of a nucleic acid is isolated for the first time.

1956

Kornberg discovers the enzyme DNA polymerase I, leading to an understanding of how DNA is replicated.

1958

Sickle cell anemia is shown to occur due to a change of a single amino acid.

DNA is made in a test tube for the first time.

1959

Systemic fungicides are developed. The steps in protein biosynthesis are delineated.

Also in the 1950s

Discovery of interferons.

First synthetic antibiotic.

1960

Exploiting base pairing, hybrid DNA-RNA molecules are created.

Messenger RNA is discovered.

1961

USDA registers first biopesticide: ***Bacillus thuringiensis,*** or Bt.

1963

New wheat varieties developed by Norman Borlaug increase yields by 70 percent.

1964

The International Rice Research Institute in the Philippines starts the Green Revolution with new strains of rice that double the yield of previous strains if given sufficient fertilizer.

1965

Harris and Watkins successfully fuse mouse and human cells.

1966

The genetic code is cracked, demonstrating that a sequence of three nucleotide bases (a codon) determines each of 20 amino acids. (Two more amino acids have since been discovered.)

1967

The first automatic protein sequencer is perfected.

1969

An enzyme is synthesized in vitro for the first time.

1970

Norman Borlaug receives the Nobel Peace Prize (see 1963).

Discovery of restriction enzymes that cut and splice genetic material, opening the way for gene cloning.

Also in the 1970s

First commercial company founded to develop genetically engineered products.

Discovery of polymerases.

Techniques for rapid sequencing of nucleotides perfected.

Gene targeting.

RNA splicing.

1971

First complete synthesis of a gene.

1972

The DNA composition of humans is discovered to be 99 percent similar to that of chimpanzees and gorillas.

Initial work with embryo transfer.

1973

Stanley Cohen and Herbert Boyer perfect techniques to cut and paste DNA (using restriction enzymes and ligases) and reproduce the new DNA in bacteria.

1974

The National Institutes of Health forms a Recombinant DNA Advisory Committee to oversee recombinant genetic research.

1975

Government first urged to develop guidelines for regulating experiments in recombinant DNA: Asilomar Conference, California.

The first monoclonal antibodies are produced.

1976

The tools of recombinant DNA are first applied to a human inherited disorder.

Molecular hybridization is used for the prenatal diagnosis of alpha thalassemia.

Yeast genes are expressed in *E. coli* bacteria.

The sequence of DNA base pairs for a specific gene is determined.

First guidelines for recombinant DNA experiments released: National Institutes of Health-Recombinant DNA Advisory Committee.

1977

First expression of human gene in bacteria.

Procedures developed for rapidly sequencing long sections of DNA using electrophoresis.

1978

High-level structure of virus first identified.

Recombinant human insulin first produced.

North Carolina scientists show it is possible to introduce specific mutations at specific sites in a DNA molecule.

1979

Human growth hormone first synthesized.

1980

The U.S. Supreme Court, in the landmark case *Diamond v. Chakrabarty,* approves the principle of patenting organisms, which allows the Exxon oil company to patent an oil-eating microorganism.

The U.S. patent for gene cloning is awarded to Cohen and Boyer.

The first gene-synthesizing machines are developed.

Researchers successfully introduce a human gene—one that codes for the protein interferon—into a bacterium.

Nobel Prize in Chemistry awarded for creation of the first recombinant molecule: Berg, Gilbert, Sanger.

1981

Scientists at Ohio University produce the first transgenic animals by transferring genes from other animals into mice.

Chinese scientist becomes the first to clone a fish—a golden carp.

1982

Applied Biosystems, Inc., introduces the first commercial gas phase protein sequencer, dramatically reducing the amount of protein sample needed for sequencing.

First recombinant DNA vaccine for livestock developed.

First biotech drug approved by FDA: human insulin produced in genetically modified bacteria.

First genetic transformation of a plant cell: petunia.

1983

The polymerase chain reaction (PCR) technique is conceived. PCR, which uses heat and enzymes to make unlimited copies of genes and gene fragments, later becomes a major tool in biotech research and product development worldwide.

The first genetic transformation of plant cells by TI plasmids is performed.

The first artificial chromosome is synthesized.

The first genetic markers for specific inherited diseases are found.

First whole plant grown from biotechnology: petunia.

First proof that modified plants pass their new traits to offspring: petunia.

1984

The DNA fingerprinting technique is developed.

The entire genome of the human immunodeficiency virus is cloned and sequenced.

1985

Genetic markers found for kidney disease and cystic fibrosis.

Genetic fingerprinting entered as evidence in a courtroom.

Transgenic plants resistant to insects, viruses and bacteria are field-tested for the first time.

The NIH approves guidelines for performing gene-therapy experiments in humans.

1986

First recombinant vaccine for humans: hepatitis B.

First anticancer drug produced through biotech: interferon.

The U.S. government publishes the ***Coordinated Framework for Regulation of Biotechnology,*** establishing more stringent regulations for rDNA organisms than for those produced with traditional genetic modification techniques.

A University of California-Berkeley chemist describes how to combine antibodies and enzymes (abzymes) to create pharmaceuticals.

The first field tests of transgenic plants (tobacco) are conducted.

The Environmental Protection Agency approves the release of the first transgenic crop—gene-altered tobacco plants.

The Organization of Economic Cooperation and Development (OECD) Group of National Experts on Safety in Biotechnology states: "Genetic changes from rDNA techniques will often have inherently greater predictability compared to traditional techniques" and "risks associated with rDNA organisms may be assessed in generally the same way as those associated with non-rDNA organisms."

1987

First approval for field test of modified food plants: virus-resistant tomatoes.

Frostban, a genetically altered bacterium that inhibits frost formation on crop plants, is field-tested on strawberry and potato plants in California, the first authorized outdoor tests of a recombinant bacterium.

1988

Harvard molecular geneticists are awarded the first U.S. patent for a genetically altered animal—a transgenic mouse.

A patent for a process to make bleach-resistant protease enzymes to use in detergents is awarded.

Congress funds the Human Genome Project, a massive effort to map and sequence the human genetic code as well as the genomes of other species.

1989

First approval for field test of modified cotton: insect-protected (Bt) cotton.

Plant Genome Project begins.

Also in the 1980s

Studies of DNA used to determine evolutionary history.

Recombinant DNA animal vaccine approved for use in Europe.

Use of microbes in oil spill cleanup: bioremediation technology.

Ribozymes and retinoblastomas identified.

1990

Chy-Max™, an artificially produced form of the chymosin enzyme for cheese-making, is

introduced. It is the first product of recombinant DNA technology in the U.S. food supply.

The Human Genome Project—an international effort to map all the genes in the human body—is launched.

The first experimental gene therapy treatment is performed successfully on a 4-year-old girl suffering from an immune disorder.

The first transgenic dairy cow—used to produce human milk proteins for infant formula—is created.

First insect-protected corn: Bt corn.

First food product of biotechnology approved in U.K.: modified yeast.

First field test of a genetically modified vertebrate: trout.

1992

American and British scientists unveil a technique for testing embryos in vitro for genetic abnormalities such as cystic fibrosis and hemophilia.

The FDA declares that transgenic foods are "not inherently dangerous" and do not require special regulation.

1993

Merging two smaller trade associations creates the Biotechnology Industry Organization (BIO).

FDA approves bovine somatotropin (BST) for increased milk production in dairy cows.

1994

First FDA approval for a whole food produced through biotechnology: FLAVRSAVR™ tomato.

The first breast cancer gene is discovered.

Approval of recombinant version of human DNase, which breaks down protein accumulation in the lungs of CF patients.

BST commercialized as POSILAC bovine somatotropin.

1995

The first baboon-to-human bone marrow transplant is performed on an AIDS patient.

The first full gene sequence of a living organism other than a virus is completed, for the bacterium *Hemophilus influenzae*.

Gene therapy, immune system modulation and recombinantly produced antibodies enter the clinic in the war against cancer.

1996

The discovery of a gene associated with Parkinson's disease provides an important new avenue of research into the cause and potential treatment of the debilitating neurological ailment.

1997

First animal cloned from an adult cell: a sheep named Dolly in Scotland.

First weed- and insect-resistant biotech crops commercialized: Roundup Ready® soybeans and Bollgard® insect-protected cotton.

Biotech crops grown commercially on nearly 5 million acres worldwide: Argentina, Australia, Canada, China, Mexico and the United States.

A group of Oregon researchers claims to have cloned two Rhesus monkeys.

1998

University of Hawaii scientists clone three generations of mice from nuclei of adult ovarian cumulus cells.

Human embryonic stem cell lines are established.

Scientists at Japan's Kinki University clone eight identical calves using cells taken from a single adult cow.

The first complete animal genome, for the *C. elegans* worm, is sequenced.

A rough draft of the human genome map is produced, showing the locations of more than 30,000 genes.

Five Southeast Asian countries form a consortium to develop disease-resistant papayas.

Also in the 1990s

First conviction using genetic fingerprinting in the U.K.

Discovery that hereditary colon cancer is caused by defective DNA repair gene.

Recombinant rabies vaccine tested in raccoons.

Biotechnology-based biopesticide approved for sale in the United States.

Patents issued for mice with specific transplanted genes.

First European patent on a transgenic animal issued for transgenic mouse sensitive to carcinogens.

2000

First complete map of a plant genome developed: *Arabidopsis thaliana.*

Biotech crops grown on 108.9 million acres in 13 countries.

"Golden rice" announcement allows the technology to be available to developing countries in hopes of improving the health of undernourished people and preventing some forms of blindness.

First biotech crop field-tested in Kenya: virus-resistant sweet potato.

Rough draft of the human genome sequence is announced.

2001

First complete map of the genome of a food plant completed: rice.

Chinese National Hybrid researchers report developing a "super rice" that could produce double the yield of normal rice.

Complete DNA sequencing of the agriculturally important bacteria, *Sinorhizobium meliloti,* a nitrogen-fixing species, and *Agrobacterium tumefaciens,* a plant pest.

A single gene from *Arabidopsis* inserted into tomato plants to create the first crop able to

grow in salty water and soil.

2002

The first draft of a functional map of the yeast proteome, an entire network of protein complexes and their interactions, is completed. A map of the yeast genome was published in 1996.

International consortia sequence the genomes of the parasite that causes malaria and the species of mosquito that transmits the parasite.

The draft version of the complete map of the human genome is published, and the first part of the Human Genome Project comes to an end ahead of schedule and under budget.

Scientists make great progress in elucidating the factors that control the differentiation of stem cells, identifying over 200 genes that are involved in the process.

Biotech crops grown on 145 million acres in 16 countries, a 12 percent increase in acreage grown in 2001. More than one-quarter (27 percent) of the global acreage was grown in nine developing countries.

Researchers announce successful results for a vaccine against cervical cancer, the first demonstration of a preventative vaccine for a type of cancer.

Scientists complete the draft sequence of the most important pathogen of rice, a fungus that destroys enough rice to feed 60 million people annually. By combining an understanding of the genomes of the fungus and rice, scientists will elucidate the molecular basis of the interactions between the plant and pathogen.

Scientists are forced to rethink their view of RNA when they discover how important small pieces of RNA are in controlling many cell functions.

2003

Researchers find a vulnerability gene for depression and make strides in detecting genetic links to schizophrenia and bipolar disorder.

GloFish, the first biotech pet, hits the North American market. Specially bred to detect water pollutants, the fish glows red under black light thanks to the addition of a natural fluorescence gene.

Worldwide biotech crop acreage rises 15 percent to hit 167.2 million acres in 18 countries. Brazil and the Philippines grow biotech crops for the first time in 2003. Also, Indonesia allows consumption of imported biotech foods and China and Uganda accept biotech crop imports.

The U.K. approves its first commercial biotech crop in eight years. The crop is a biotech herbicide-resistant corn used for cattle feed.

The U.S. Environmental Protection Agency approves the first transgenic rootworm-resistant corn, which may save farmers $1 billion annually in crop losses and pesticide use.

An endangered species (the banteng) is cloned for the first time. 2003 also brought several other cloning firsts, including mules, horses and deer.

Dolly, the cloned sheep that made headlines in 1997, is euthanized after developing

progressive lung disease. Dolly was the first successful clone of a mammal.

Japanese researchers develop a biotech coffee bean that is naturally decaffeinated.

2004

A group of Korean researchers report the first human embryonic stem cell line produced with somatic cell nuclear transfer (cloning).

The FDA approves the first anti-angiogenic drug for cancer, Avastin (bevacizumab).

The FDA clears the first DNA microarray test system, the AmpliChip Cytochrome P450 Genotyping Test, to aid in selecting medications and disease for a wide variety of common conditions.

An RNA-interference product for age-related "wet" macular degeneration becomes the first RNAi product to enter a clinical trial.

The United Nations Food and Agriculture Organization (FAO) endorses biotech crops and states that biotechnology is a complementary tool to traditional farming methods that can help poor farmers and consumers in developing nations.

The National Academy of Sciences' Institute of Medicine (IOM) finds biotech crops do not pose any more health risks than do crops created by other techniques, and that food safety evaluations should be based on the resulting food product, not the technique used to create it.

FDA finds biotech wheat safe, after a food safety review.

Monsanto introduces lowlinolenic soybeans (produced through conventional breeding methods) that will reduce or eliminate trans fatty acids in processed soybean oil.

Chicken genome sequenced by the Chicken Genome Sequencing Consortium.

First cloned pet, a kitten, delivered to its owner.

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Appendix IV: cGMP

Current Good Manufacturing Practices

The Regulatory Environment for Biological Pharmaceutical Manufacturing[1]

Human therapeutic and vaccine proteins produced utilizing modern biotechnology methods, often using recombinant DNA technology, are termed biological pharmaceuticals or "biologics". Thus, their manufacture and production falls under the scrutiny of the Food and Drug Administration. The production of recombinant human proteins requires the strictest regulation since these products are most often administered intravenously or by injection. Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs is regulated by the FDA under the Code of Federal Regulations (CFR) 21 CFR 210 and 211. Additional regulations can be found in 21CFR600 and 610, and comments can be found in documents periodically released by the FDA entitled "Points to Consider".

cGMP delineates the requirements for drug manufacturing and production including requirements for the personnel, buildings and facilities, equipment, production and process control, packaging and labeling, holding and distribution, records and reports and what to do with returned and salvaged drug products. cGMP requires a quality documentation system that serve as a communication system to ensure that everyone in the company is marching to the same beat. Documentation takes the form of descriptive documents such as standard operating procedures, protocols, and master production records which describe how to perform certain tasks; data collection documents such as forms, reports, production batch records and log books that document tasks and events; numbering systems such as part numbers, lot numbers, equipment numbers, form numbers, and SOP numbers which serve to account for and track information; and data files including equipment history files, facility qualification files, and product files which serve to organize the data into useful categories of concern for review and to support accountability and traceability requirements.

For this course, the most important aspects of cGMP pertain to the tools and processes (fermentation or upstream processing, purification or downstream processing, and quality control) involved in the manufacture and production of an injectable protein pharmaceutical; and include descriptive documents, especially SOPs; data collection documents, especially production batch records and log books; and numbering systems. Finally the start-up in the production of a new protein product and/or a new facility requires the establishment of validation protocols for equipment and utility systems, methods and processes.

Now we will describe some of these important documents:

Standard Operating Procedure (SOP)

Standard Operating Procedures (SOPs) are documents that describe how to perform various routine procedures in a cGMP facility. SOPs relate to both tools and equipment. SOPs contain step-by-step instructions that technicians in production, QC, maintenance and material handling must consult daily in order to complete their tasks reliably and consistently. SOPs, therefore, are written commitments to the FDA that describe the performance of a routine task. An FDA inspection evaluates how well these written commitments are fulfilled. SOPs make it clear how the task will be performed (procedure), who will perform the task (responsibility), why it will be performed (purpose), and what limits of use apply (scope). Finally, SOPs are drafted and revised by the individuals that perform the operations.

Master Production Batch Record (MPBR) or Production Batch Record (PBR)

A master production batch records (MPBR) is a detailed, step-by-step description of the entire production process for a specific drug. It is the document wherein the chemical and biological processes of drug manufacturing (developed during the phase of research and process development of the drug) are merged with the regulatory requirements of the FDA. A good batch record ensures the fundamentals of cGMP compliance while providing a practical set of instructions for the manufacturing technician or operator. The MPBR explains exactly how the product is produced, indicating specific types and quantities of components and raw materials, processing parameters, in-process quality controls, environmental controls, etc. To support the requirements of the production batch record (PBR) which is also known as the batch production and control record, the MPBR contains fill-in-the-blank spaces throughout the text to facilitate the documentation of events for each individual batch. In fact the PBR is an

exact copy of an approved MPBR. A PBR is issued for each batch of product produced in the facility. A batch, by the way, is defined in the Code of Federal Regulations, Title 21 210.3: "Batch means a specific quantity of a drug or other material that is intended to have a uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacturing." For a cell-culture derived protein product, a batch begins with inoculation and then proceeds through harvest and purification (sometimes the final purification steps may have a separate batch record). There would be separate batch records for media preparation, equipment preparation (cleaning, assembly, sterilization, etc.), and scale-up for inoculums preparation. There would also be separate batch records for final product formulation, filtration, filling, lyophilization, sealing, inspection, and labeling. PBRs must be followed during production events, and the information and signature blocks must be completed as production proceeds. Production and QC personnel write the MPBR. This might very well be you.

When a PBR has been completed, the production manager collects all associated and supporting documents including QC records, sterilization charts, lyophilization charts, environmental monitoring records and inspection reports. This is the product file or record. Any deviations are brought forward for discussion or investigation. Final release of product occurs when the entire product record has been reviewed and found to be acceptable by production, QC and QA departments. The product record is then secured and can be used to support the company if any problems with the drug arise.

Log Book

Log books are maintained so that a chronological record of all equipment-related activities can be maintained. There are log books for equipment operation, and room usage, and cleaning. The log book provides easy access to information about equipment and room status at any given moment in time. Equipment log books are kept for all major equipment in a cGMP facility including boilers, water-for-injection (WFI) stills, bioreactors, sterilizers, chromatography columns, etc. Room cleaning and use log books are kept for clean rooms. Minimum log book entries include date, time, the name of the technician and the event, but could also include a list of tasks that permits the technician to check off, sign, and date each event in the list of tasks as s/he performs them.

Numbering System

A numbering system is used to identify all items in the cGMP manufacturing facility that are part of a product or come in direct contact with the final product during processing including vials, stoppers, seals, cells, media, growth factors, bioreactors, and reagents. The rationale for using such a numbering system is that it is far more convenient to cite a part number than to write the part out in long hand. Also, numbers are easier to track when troubleshooting a problem arising during manufacturing and production. Items such as aluminum foil, laboratory notebooks and general glassware are not assigned numbers.

Validation Protocols

Finally, important to the start-up of manufacturing and production of a given protein or the start-up of a facility are validation protocols covering three major categories: equipment and utility systems; methods; and processes. Three major types of evaluation are undertaken in a validation protocol: installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ). A validation protocol is completed when all three qualification procedures have been completed, in order, and all acceptable criteria have been met. The following shows the type of information that needs to be collected to prepare IQ's, OQ's and PQ's for a piece of equipment. The same type of information would be collected in order to complete a validation protocol for a method or a process. The FDA has specifically defined process validation: **"Process validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics."**

IQ

For a piece of equipment to be validated the IQ would contain **equipment identification information** such as the manufacturer's model and serial numbers, equipment size, dimensions, weight, capacity, and location in the facility; **equipment utility requirements** including services such as water, electric, gas, compressed air, steam, nitrogen, drain and exhaust lines, the quality and quantity of feed utilities, and specific requirements such

as pipe composition, diameter, and filter requirements; and **equipment safety features** including pressure relief valves and alarms and the settings at which the alarms are designed to activate.

OQ

For a piece of equipment to be validated the OQ would contain **calibration requirements** indicating the parameters to be measured, how they will be measured or monitored, and what is the acceptable range or limit; **preoperational activities** including cleaning and sanitization of piping systems, passivation of stainless steel tanks and/or distribution lines, performance of heating elements, door gasket integrity, and software checks; **operations criteria** would describe how to exercise all electromechanical operations on the equipment and describe acceptance performance. (An autoclave OQ, for example, would include a description of each cycle, directions for starting the cycle and acceptable results of cycle monitoring. In addition, uniform heat distribution throughout the chamber would have to be demonstrated by collecting data from thermocouples distributed throughout the chamber.); and **acceptance criteria** for the OQ must be stated in the validation protocol.

PQ

Once a piece of equipment is properly installed and functioning within specific operating parameters, it must be demonstrated that it can perform reliably and reproducibly, even under worst-case conditions. For a piece of equipment to be validated the PQ would contain **preliminary operations** including the validation of routine processing conditions during which minimum and maximum conditions for routine processing are determined; **performance qualification procedures** which demonstrate that the equipment or utility system can consistently meet the operating specifications and perform its intended function during three consecutive, successful cycles; and **performance qualification acceptance criteria** which ensure that all processing parameters meet the specifications cited in the validation protocol, that the raw data are available to support these claims, and that the number of consecutive runs meets requirements.

With the description and explanation given above now different divisions in the manufacturing are considered and related priority topics have been given.

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- The Code of Federal Regulations for the Food and Drug Administration Current Good Manufacturing Practices is CFR #21 Parts 210 and 211 and may be found at http://www.fda.gov/cder

Appendix V: Glossary

A

Acclimatization
Adaptation of an organism to a new environment.
Action letter
An official FDA communication that informs an NDA or BLA sponsor of a decision by the agency. An approval letter allows commercial marketing of the product.
Active immunity
A type of acquired immunity whereby resistance to a disease is built up by either having the disease or receiving a vaccine to it.
Adjuvant
Insoluble material that increases the formation and persistence of antibodies when injected with an antigen.
Aerobic
Needing oxygen for growth.
Agrobacterium tumefaciens
A common soil bacterium used as a vector to create transgenic plants.
Allele
Any of several alternative forms of a gene.
Allogenic
Of the same species, but with a different genotype. Also *allogeneic*.
Alzheimer's disease
A disease characterized by, among other things, progressive loss of memory. The development of Alzheimer's disease is thought to be associated, in part, with possessing certain alleles of the gene that encodes apolipoprotein E.
Amino acids
Building blocks of proteins. There are 20 common amino acids: alanine, arginine, aspargine, aspartic acid, cysteine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine. Two more amino acids have been discovered in microbes: selenocysteine and pyrrolysine.
Amplification
The process of increasing the number of copies of a particular gene or chromosomal sequence.
Anaerobic
Growing in the absence of oxygen.
Antibiotic
Chemical substance formed as a metabolic byproduct in bacteria or fungi and used to treat bacterial infections. Antibiotics can be produced naturally, using microorganisms, or synthetically.
Antibody
Protein produced by humans and higher animals in response to the presence of a specific antigen.
Anticodon
Triplet of nucleotide bases (codon) in transfer RNA that pairs with (is complementary to) a triplet in messenger RNA. For example, if the codon is UCG, the anticodon is AGC. See also *Base*; *Base pair*; *Complementarity*.
Antigen
A substance that, when introduced into the body, induces an immune response by a specific antibody.
Antigenic determinant
See *Hapten*.
Antihemophilic factors
A family of whole-blood proteins that initiate blood clotting. Some of these proteins, such as factor VIII, can be used to treat hemophilia. See also *Factor VIII*; *Kidney plasminogen activator*.

Antisense
A piece of DNA producing a mirror image ("antisense") messenger RNA that is opposite in sequence to one directing protein synthesis. Antisense technology is used to selectively turn off production of certain proteins.
Antiserum
Blood serum containing specific antibodies against an antigen. Antisera are used to confer passive immunity to many diseases.
Apolipoprotein E (Apo E)
Certain alleles of the gene that encodes the protein apolipoprotein E have been associated with the development of heart disease and Alzheimer's disease.
Assay
Technique for measuring a biological or any other response. It is an analytical technique for estimation and understanding composition of substances.
Attenuated
Weakened; with reference to vaccines, made from pathogenic organisms that have been treated so as to render them avirulent.
Autoimmune disease
A disease in which the body produces antibodies against its own tissues.
Autoimmunity
A condition in which the body mounts an immune response against one of its own organs or tissues.
Autosome
Any chromosome other than a sex chromosome.
Avirulent
Unable to cause disease.

B

Bacillus subtilis
A bacterium commonly used as a host in recombinant DNA experiments. Important because of its ability to secrete proteins.
Bacillus thuringiensis (*Bt*)
Naturally occurring soil bacterium that generates a protein toxic to a variety of lepidoptera, such as corn borers, but is harmless to people and animals.
Bacteriophage
Virus that lives in and kills bacteria. Also called *phage*.
Bacterium
Any of a large group of microscopic organisms with a very simple cell structure. Some manufacture their own food, some live as parasites on other organisms, and some live on decaying matter.
Base
A key component of DNA and RNA molecules. Four different bases are found in DNA: adenine (A), cytosine (C), guanine (G) and thymine (T). In RNA, uracil (U) substitutes for thymine. Also known as nitrogenous bases. A base, a phosphate molecule and a sugar joined together constitute a nucleotide.
Base pair
Two nucleotide bases on different strands of the nucleic acid molecule that bond together. The bases can pair in only one way: adenine with thymine (DNA) or uracil (RNA), and guanine with cytosine.
Bioassay
Determination of the effectiveness of a compound by measuring its effect on animals, tissues or organisms in comparison with a standard preparation.
Bioaugmentation
Increasing the activity of bacteria that break down pollutants by adding more of their kind. A technique used in bioremediation.
Biocatalyst
In bioprocessing, an enzyme that activates or speeds up a biochemical reaction.
Biochemical
The product of a chemical reaction in a living organism.

Biochip
An electronic device that uses organic molecules to form a semiconductor.
Bioconversion
Chemical restructuring of raw materials by using a biocatalyst.
Biodegradable
Capable of being reduced to water and carbon dioxide by the action of microorganisms.
Bioenrichment
A bioremediation strategy that involves adding nutrients or oxygen, thereby bolstering the activity of microbes as they break down pollutants.
Bioinformatics
The science of informatics as applied to biological research. Informatics is the management and analysis of data using advanced computing techniques. Bioinformatics is particularly important as an adjunct to genomics research, because of the large amount of complex data this research generates.
Biolistic device
A device that shoots microscopic DNA-coated particles into target cells.
Biological oxygen demand (BOD)
The amount of oxygen used for growth by organisms in water that contains organic matter.
Biologic (Biologic response modifier)
A substance that alters the growth or functioning of a cell. Includes hormones and compounds that affect the nervous and immune systems.
Biomass
The totality of biological matter in a given area. As commonly used in biotechnology, refers to the use of cellulose, a renewable resource, for the production of chemicals that can be used to generate energy or as alternative feedstocks for the chemical industry to reduce dependence on nonrenewable fossil fuels.
Biomaterials
Biological molecules, such as proteins and complex sugars, used to make medical devices, including structural elements used in reconstructive surgery.
Bioprocess
A process in which living cells, or components thereof, are used to produce a desired product.
Bioreactor
Vessel used for bioprocessing.
Bioremediation
The use of microorganisms to remedy environmental problems, rendering hazardous wastes nonhazardous.
Biosynthesis
Production of a chemical by a living organism.
Biotechnology
The use of biological processes to solve problems or make useful products.
Biotransformation
The use of enzymes in chemical synthesis to produce chemical compounds of a desired stereochemistry.
Blastocyst (Blastula)
The 4- to 5-day-old ball of undifferentiated cells from which a prospective embryo develops. In mammals it consists of two distinct parts: the inner cell mass and the trophoblast.
B lymphocytes (B-cells)
A class of lymphocytes, released from the bone marrow, that produce antibodies.
Bovine somatotropin (BST)
A hormone secreted by the bovine pituitary gland. It is used to increase milk production by improving the feed efficiency in dairy cattle milk. Also called *bovine growth hormone*.
BRCA1 and BRCA2
(BReast CAncer genes 1 and 2)
Two genes that normally help to restrain cell growth, but which can contain certain genetic mutations associated with the development of breast and ovarian cancer. Note, however, that inherited BRCA1 and BRCA2 mutations are thought to account for less than 10 percent of all breast and ovarian cancers. Recent evidence suggests that somatic cell genetic mutations (i.e.,

non-inherited genetic mutations) in these two genes may also play a role in the development of cancer.

C

Callus
A cluster of undifferentiated plant cells that can, in some species, be induced to form the whole plant.
Carbohydrate
A type of biological molecule composed of simple sugars such as glucose. Common examples include starch and cellulose.
Carcinogen
Cancer-causing agent.
Catalyst
An agent (such as an enzyme or a metallic complex) that facilitates a reaction but is not itself changed during the reaction.
Cell
The smallest structural unit of a living organism that can grow and reproduce independently.
Cell culture
Growth of cells under laboratory conditions.
Cell fusion
See *Fusion*.
Cell line
Cells that grow and replicate continuously outside the living organism.
Cell-mediated immunity
Acquired immunity in which T lymphocytes play a predominant role. Development of the thymus in early life is critical to the proper development and functioning of cell-mediated immunity.
Chemical genomics
Using structural and functional genomic information about biological molecules, especially proteins, to identify useful small molecules and alter their structure to improve their efficacy.
Chimera
The individual (animal or lower organism) produced by grafting an embryonic part of one individual onto an embryo of either the same or a different species.
Chromosomes
Threadlike components in the cell that contain DNA and proteins. Genes are carried on the chromosomes.
Clinical studies
Human studies that are designed to measure the efficacy of a new drug or biologic. Clinical studies routinely involve the use of a placebo group that is given an inactive substance that looks like the test product.
Clone
A term that is applied to genes, cells or entire organisms that are derived from — and are genetically identical to — a single common ancestor gene, cell or organism, respectively. Cloning of genes and cells to create many copies in the laboratory is a common procedure essential for biomedical research. Note that several processes commonly described as cell "cloning" give rise to cells that are almost but not completely genetically identical to the ancestor cell. Cloning of organisms from embryonic cells occurs naturally in nature (e.g., identical twins). Researchers have achieved laboratory cloning using genetic material from adult animals of several species including mice, pigs and sheep.
Codon
A sequence of three nucleotide bases that specifies an amino acid or represents a signal to stop or start a function.
Co-enzyme
An organic compound that is necessary for the functioning of an enzyme. Co-enzymes are smaller than the enzymes themselves and sometimes separable from them.
Co-factor
A nonprotein substance required for certain enzymes to function. Co-factors can be co-enzymes or metallic icons.

Colony-stimulating factors (CSFs)
A group of lymphokines that induce the maturation and proliferation of white blood cells from the primitive cell types present in bone marrow.
Combinatorial chemistry
A product discovery technique that uses robotics and parallel synthesis to generate and screen quickly as many as several million molecules with similar structure in order to find chemical molecules with desired properties.
Co-metabolism
A microbe oxidizing not only its main energy source but also another organic compound.
Complementarity
The relationship of the nucleotide bases on two different strands of DNA or RNA. When the bases are paired properly (adenine with thymine [DNA] or uracil [RNA]; guanine with cytosine), the strands are complementary.
Complementary DNA (cDNA)
DNA synthesized from a messenger RNA rather than from a DNA template. This type of DNA is used for cloning or as a DNA probe for locating specific genes in DNA hybridization studies.
Computational biology
A subdiscipline within bioinformatics concerned with computation-based research devoted to understanding basic biological processes.
Conjugation
Sexual reproduction of bacterial cells in which there is a one-way exchange of genetic material between the cells in contact.
Crossing over
Exchange of genes between two paired chromosomes.
Cross-licensing
Legal, contractual procedure in which two or more firms with competing, similar technologies and possible conflicting patent claims strike a deal to reduce the need for legal actions to clarify who is to profit from applications of the technology.
Culture
As a noun, cultivation of living organisms in prepared medium; as a verb, to grow in prepared medium.
Culture medium
Any nutrient system for the artificial cultivation of bacteria or other cells; usually a complex mixture of organic and inorganic materials.
Cyto-
Referring to cell or cell plasm.
Cytogenetics
Study of the cell and its heredity-related components, especially chromosomes.
Cytoplasm
Cellular material that is within the cell membrane and surrounds the nucleus.
Cytotoxic
Able to cause cell death.

D

Deoxyribonucleic acid (DNA)
The molecule that carries the genetic information for most living systems. The DNA molecule consists of four bases (adenine, cytosine, guanine and thymine) and a sugar-phosphate backbone, arranged in two connected strands to form a double helix. See also *Complementary DNA*; *Double helix*; *Recombinant DNA*.
Differentiation
The process of biochemical and structural changes by which cells become specialized in form and function.
Diploid
A cell with two complete sets of chromosomes. Compare *Haploid*.
DNA chip
A small piece of glass or silicon that has small pieces of DNA arrayed on its surface.
DNA fingerprinting
The use of restriction enzymes to measure the genetic variation of individuals. This technology

is often used as a forensic tool to detect differences or similarities in blood and tissue samples at crime scenes.

DNA hybridization

The formation of a double-stranded nucleic acid molecule from two separate strands. The term also applies to a molecular technique that uses one nucleic acid strand to locate another.

DNA library

A collection of cloned DNA fragments that collectively represent the genome of an organism.

DNA polymerase

An enzyme that replicates DNA. DNA polymerase is the basis of PCR — the polymerase chain reaction.

DNA probe

A small piece of nucleic acid that has been labeled with a radioactive isotope, dye or enzyme and is used to locate a particular nucleotide sequence or gene on a DNA molecule.

DNA repair enzymes

Proteins that recognize and repair certain abnormalities in DNA.

DNA sequence

The order of nucleotide bases in the DNA molecule.

DNA vaccines

Pieces of foreign DNA that are injected into an organism to trigger an immune response.

Double helix

A term often used to describe the configuration of the DNA molecule. The helix consists of two spiraling strands of nucleotides (a sugar, phosphate and base) joined crosswise by specific paring of the bases. See also *Deoxyribonucleic acid*; *Base*; *Base pair*.

Diagnostic

A product used for the diagnosis of disease or medical condition. Both monoclonal antibodies and DNA probes are useful diagnostic products.

Drug delivery

The process by which a formulated drug is administered to the patient. Traditional routes have been oral or intravenous perfusion. New methods deliver through the skin with a transdermal patch or across the nasal membrane with an aerosol spray.

E

Electrophoresis

A technique for separating different types of molecules based on their patterns of movement in an electrical field.

Electroporation

The creation of reversible small holes in a cell wall or membrane through which foreign DNA can pass. This DNA can then integrate into the cell's genome.

Enzyme-linked immunosorbent assay (ELISA)

A technique for detecting specific proteins by using antibodies linked to enzymes.

Embryonic stem cells

Cells that can give rise to any type of differentiated cell. They can be derived from two sources: the inner cell mass from a blastocyt or the primordial germ cells (eggs and sperm) of an older embryo.

Endostatin

An endogenous protein that blocks the proliferation of blood vessels.

Enzyme

A protein catalyst that facilitates specific chemical or metabolic reactions necessary for cell growth and reproduction.

Erythropoietin (EPO)

A protein that boosts production of red blood cells. It is clinically useful in treating certain types of anemia.

Escherichia coli (E. coli)

A bacterium that inhabits the intestinal tract of most vertebrates. Much of the work using recombinant DNA techniques has been carried out with this organism because it has been genetically well characterized.

Eukaryote
A cell or organism containing a true nucleus, with a well-defined membrane surrounding the nucleus. All organisms except bacteria, viruses and cyanobacteria are eukaryotic. Compare *Prokaryote*.
Exon
In eukaryotic cells, that part of the gene that is transcribed into messenger RNA and encodes a protein. See also *Intron*; *Splicing*.
Expression
In genetics, manifestation of a characteristic that is specified by a gene. With hereditary disease, for example, a person can carry the gene for the disease but not actually have the disease. In this case, the gene is present but not expressed. In industrial biotechnology, the term is often used to mean the production of a protein by a gene that has been inserted into a new host organism.
Extremophiles
Microorganisms that live at extreme levels of pH, temperature, pressure and salinity.

F

Factor VIII
A large, complex protein that aids in blood clotting and is used to treat hemophilia. See also *Antihemophilic factors*.
Feedstock
The raw material used for chemical or biological processes.
Fermentation
The process of growing microorganisms for the production of various chemical or pharmaceutical compounds. Microbes are normally incubated under specific conditions in the presence of nutrients in large tanks called fermentors.
Functional foods
Foods containing compounds with beneficial health effects beyond those provided by the basic nutrients, minerals and vitamins. Also called *nutraceuticals*.
Functional genomics
A field of research that aims to understand what each gene does, how it is regulated and how it interacts with other genes.
Fusion
Joining of the membrane of two cells, thus creating a daughter cell that contains some of the same properties from each parent cells. Used in making hybridomas.

G

Gel electrophoresis
A process for separating molecules by forcing them to migrate through a gel under the influence of an electric field.
Gene
A segment of chromosome. Some genes direct the syntheses of proteins, while others have regulatory functions. See also *Operator gene*; *Structural gene*; *Suppressor gene*.
Gene amplification
The increase, within a cell, of the number of copies of a given gene.
Gene knockout
The replacement of a normal gene with a mutated form of the gene by using homologous recombination. Used to study gene function.
Gene machine
A computerized device for synthesizing genes by combing nucleotides (bases) in the proper order.
Gene mapping
Determination of the relative locations of genes on a chromosome.
Gene sequencing
Determination of the sequence of nucleotide bases in a strand of DNA. See also *Sequencing*.
Gene therapy
The replacement of a defective gene in an organism suffering from a genetic disease. Recombinant DNA techniques are used to isolate the functioning gene and insert it into cells.

More than 300 single-gene genetic disorders have been identified in humans. A significant percentage of these may be amenable to gene therapy.

Genetic code

The code by which genetic information in DNA is translated into biological function. A set of three nucleotides (codons), the building blocks of DNA, signifies one amino acid, the building blocks of proteins.

Genetic modification

A number of techniques, such as selective breeding, mutagenesis, transposon insertions and recombinant DNA technology, that are used to alter the genetic material of cells in order to make them capable of producing new substances, performing new functions or blocking the production of substances.

Genetic predisposition

Susceptibility to disease that is related to a genetic predisposition mutation, which may or may not result in actual development of the disease.

Genetic screening

The use of a specific biological test to screen for inherited diseases or medical conditions. Testing can be conducted prenatally to check for metabolic defects and congenital disorders in the developing fetus as well as postnatally to screen for carriers of heritable diseases.

Genetic testing

The analysis of an individual's genetic material. Genetic testing can be used to gather information on an individual's genetic predisposition to a particular health condition, or to confirm a diagnosis of genetic disease.

Genome

The total hereditary material of a cell, comprising the entire chromosomal set found in each nucleus of a given species.

Genomics

The study of genes and their function. Recent advances in genomics are bringing about a revolution in our understanding of the molecular mechanisms of disease, including the complex interplay of genetic and environmental factors. Genomics is also stimulating the discovery of breakthrough health-care products by revealing thousands of new biological targets for the development of drugs and by giving scientists innovative ways to design new drugs, vaccines and DNA diagnostics. Genomic-based therapeutics may include "traditional" small chemical drugs, protein drugs and gene therapy.

Genotype

Genetic makeup of an individual or group. Compare *Phenotype*.

Germ cell

Reproductive cell (sperm or egg). Also called *gamete* or *sex cell*.

Germplasm

The total genetic variability, represented by germ cells or seeds, available to a particular population of organisms.

Glycoprotein

A protein conjugated with a carbohydrate group.

Granulocyte

One of three types of white blood cells. Granulocytes digest bacteria and other parasites.

Granulocyte-macrophage colony stimulating factor (GMCSF)

A natural hormone that stimulates white blood cell production, particularly that of granulocytes and monocytes (the precursors of macrophages).

Growth factors

Naturally occurring proteins that stimulate the growth and reproduction of specific cell types. Growth factors are essential to regenerative medicine and tissue engineering.

Growth hormone

A protein produced by the pituitary gland that is involved in cell growth. Human growth hormone is used clinically to treat dwarfism. Various animal growth hormones can be used to improve milk production as well as produce a leaner variety of meat. Also called *somatotropin*.

H

Haploid
A cell with half the usual number of chromosomes, or only one chromosome set. Sex cells are haploid. Compare *Diploid*.
Hapten
The portion of an antigen that determines its immunological specificity. When coupled to a large protein, a hapten stimulates the formation of antibodies to the two-molecule complex. Also called *antigenic determinant*.
Hemagglutination
Clumping (agglutination) of red blood cells.
Heredity
Transfer of genetic information from parent cells to progeny.
Histocompatibility
Immunologic similarity of tissues such that grafting can be done without tissue rejection.
Histocompatibility antigen
An antigen that causes the rejection of grafted material from an animal different in genotype from the host animal.
Homeobox
Family of genes that regulates activities of other genes (turns genes on and off).
Homologous
Corresponding or alike in structure, position or origin.
Hormone
A chemical or protein that acts as a messenger or stimulatory signal, relaying instructions to stop or start certain physiological activities. Hormones are synthesized in one type of cell and then released to direct the function of other cell types.
Host
A cell or organism used for growth of a virus, plasmid or other form of foreign DNA, or for the production of cloned substances.
Host-vector system
Combination of DNA-receiving cells (host) and DNA-transporting substance (vector) used for introducing foreign DNA into a cell.
Human Genome Project
An international research effort aimed at discovering the full sequence of bases in the human genome. Led in the United States by the National Institutes of Health and the Department of Energy.
Human immunodeficiency virus (HIV)
The virus that causes acquired immune deficiency syndrome (AIDS).
Hybridization
Production of offspring, or hybrids, from genetically dissimilar parents. The process can be used to produce hybrid plants (by crossbreeding two different varieties) or hybridomas (hybrid cells formed by fusing two unlike cells, used in producing monoclonal antibodies). See *DNA hybridization*.
Hybridoma
The cell produced by fusing two cells of different origin. In monoclonal antibody technology, hybridomas are formed by fusing an immortal cell (one that divides continuously) and an antibody-producing cell. See also *Monoclonal antibody*; *Myeloma*.

I

Immune response
The response of the immune system to challenge by a foreign antigen.
Immune serum
Blood serum containing antibodies.
Immune system
The combination of cells, biological substances (such as antibodies) and cellular activities that work together to provide resistance to disease.
Immunity
Nonsusceptibility to a disease or to the toxic effects of antigenic material. See also *Active immunity*; *Cell-mediated immunity*; *Natural active immunity*; *Natural passive immunity*; *Passive immunity*.

Immunoassay
Technique for identifying substances based on the use of antibodies.
Immunodiagnostics
The use of specific antibodies to measure a substance. This tool is useful in diagnosing infectious diseases and the presence of foreign substances in a variety of human and animal fluids (blood, urine, etc.). It is currently being investigated as a way of locating tumor cells in the body.
Immunofluorescence
Technique for identifying antigenic material that uses an antibody labeled with fluorescent material. Specific binding of the antibody and antigen can be seen under a microscope by applying ultraviolet light rays and noting the visible light that is produced.
Immunogen
Any substance that can elicit an immune response.
Immunoglobulin
General name for proteins that function as antibodies. These proteins differ somewhat in structure and are grouped into five categories on the basis of these differences; immunoglobulin G (IgG), IgM, IgA, IgE and IgD.
Immunology
Study of all phenomena related to the body's response to antigenic challenge (i.e., immunity, sensitivity and allergy).
Immunomodulators
A diverse class of proteins that boost the immune system. Many are cell growth factors that accelerate the production of specific cells that are important in mounting an immune response in the body. These proteins are being investigated for use in possible cures for cancer.
Immunotoxins
Specific monoclonal antibodies that have a protein toxin molecule attached. The monoclonal antibody is targeted against a tumor cell, and the toxin is designed to kill that cell when the antibody binds to it.
Inducer
A molecule or substance that increases the rate of enzyme synthesis, usually by blocking the action of the corresponding repressor.
In situ
In its original or natural place or position.
Interferon
A class of lymphokine proteins important in the immune response. There are three major types of interferon: alpha (leukocyte), beta (fibroblast) and gamma (immune). Interferons inhibit viral infections and may have anticancer properties.
Interleukin
A type of lymphokine that regulates the growth and development of white blood cells. Twelve interleukins (IL-1 through IL-12) have been identified to date.
Intron
In eukaryotic cells, a sequence of DNA that is contained in the gene but does not encode for protein. The presence of introns "splits" the coding region of the gene into segments called exons. See also *Exon; Splicing*.
Investigational New Drug Application (IND)
An application to begin studies of a new drug or biologic on humans. The IND gives the plan for the study and contains formulation, manufacturing and animal test result information.
In vitro
Literally, "in glass." Performed in a test tube or other laboratory apparatus.
In vivo
In the living organism.
Islet cells
Pancreatic cells that are the source of insulin and two other hormones involved in regulating glucose metabolism and absorption.
Isoenzyme
One of the several forms that a given enzyme can take. The forms may differ in certain physical properties, but function similarly as biocatalysts.

Isogenic
Of the same genotype.

K

Kidney plasminogen activator
A precursor to the enzyme urokinase that has blood-clotting properties.

L

Leukocyte
A colorless cell in the blood, lymph and tissues that is an important component of the body's immune system. Also called *white blood cells*.

Library
A set of cloned DNA fragments that taken collectively contain the entire genome of an organism. Also called a *DNA library*.

Ligase
An enzyme used to join DNA or RNA segments together. They are called DNA ligase or RNA ligase, respectively.

Linkage
The tendency for certain genes to be inherited together due to their physical proximity on the chromosome.

Linker
A fragment of DNA with a restriction site that can be used to join DNA strands.

Lipoproteins
A class of serum proteins that transport lipids and cholesterol in the blood stream. Abnormalities in lipoprotein metabolism have been implicated in certain heart diseases.

Lymphocyte
A type of leukocyte found in lymphatic tissue in the blood, lymph nodes and organs. Lymphocytes are continuously made in the bone marrow and mature into antibody-forming cells. See also *B lymphocytes*; *T lymphocytes*.

Lymphokine
A class of soluble proteins produced by white blood cells that play a role, as yet not fully understood, in the immune response. See also *Interferon; Interleukin*.

Lymphoma
Form of cancer that affects the lymph tissue.

M

Macrophage
A type of white blood cell produced in blood vessels and loose connective tissues that can ingest dead tissues and cells and is involved in producing interleukin-1. When exposed to the lymphokine macrophage-activating factor, macrophages also kill tumor cells. See also *Phagocyte*.

Macrophage colony stimulating factor (M-CSF)
A natural hormone that stimulates the production of white blood cells, particularly monocytes (the precursors of macrophages).

Medium
A substance containing nutrients needed for cell growth.

Meiosis
Process of cell reproduction whereby the daughter cells have half the chromosome number of the parent cells. Sex cells are formed by meiosis. Compare *Mitosis*.

Messenger RNA (mRNA)
Nucleic acid that carries instructions to a ribosome for the synthesis of a particular protein.

Metabolism
All biochemical activities carried out by an organism to maintain life.

Microbial herbicides and pesticides
Microorganisms that are toxic to specific plants or insects. Because of their narrow host range and limited toxicity, these microorganisms may be preferable to their chemical counterparts for certain pest control applications.

Microbiology
Study of living organisms that can be seen only under a microscope.

Microinjection
The injection of DNA using a very fine needle into a cell.
Microorganism
Any organism that can be seen only with the aid of a microscope. Also called *microbe*.
Microtome
Microtomes are devices for cutting very thin slices to be examined under the microscope. They are sophisticated instruments and provide a bridge between technology and biology.
Mitosis
Process of cell reproduction whereby the daughter cells are identical in chromosome number to the parent cells. Compare *Meiosis*.
Molecular genetics
Study of how genes function to control cellular activities.
Monoclonal antibody (MAb)
Highly specific, purified antibody that is derived from only one clone of cells and recognizes only one antigen. See also *Hybridoma*; *Myeloma*.
Monocytes
One of three types of white blood cells. Monocytes are precursors to macrophages.
Multigenic
Of hereditary characteristics, one that is specified by several genes.
Mutagen
A substance that induces mutations.
Mutant
A cell that manifests new characteristics due to a change in its DNA.
Mutation
A change in the genetic material of a cell.
Myeloma
A type of tumor cell that is used in monoclonal antibody technology to form hybridomas.

N

Natural active immunity
Immunity that is established after the occurrence of a disease.
Natural killer cell (NK)
A type of leukocyte that attacks cancerous or virus-infected cells without previous exposure to the antigen. NK cell activity is stimulated by interferon.
Natural passive immunity
Immunity conferred by the mother on the fetus or newborn.
Nitrogen fixation
A biological process (usually associated with plants) whereby certain bacteria convert nitrogen in the air to ammonia, thus forming a nutrient essential for growth.
Nitrogenous base
See *Base*.
Noncoding DNA
DNA that does not encode any product (RNA or protein). The majority of the DNA in plants and animals is noncoding.
Nuclease
An enzyme that, by cleaving chemical bonds, breaks down nucleic acids into their constituent nucleotides.
Nucleic acids
Large molecules, generally found in the cell's nucleus and/or cytoplasm, that are made up of nucleotides. The two most common nucleic acids are DNA and RNA.
Nucleotides
The building blocks of nucleic acids. Each nucleotide is composed of sugar, phosphate and one of four nitrogen bases. The sugar in DNA is deoxyribose and RNA's sugar is ribose. The sequence of the bases within the nucleic acid determines the sequence of amino acids in a protein. See also *Base*.
Nucleus
The structure within eukaryotic cells that contains chromosomal DNA.

O

Oligonucleotide
A polymer consisting of a small number (about two to 10) of nucleotides.
Oncogene
Gene thought to be capable of producing cancer.
Oncogenic
Cancer causing.
Oncology
Study of tumors.
Operator gene
A region of the chromosome, adjacent to the operon, where a repressor protein binds to prevent transcription of the operon.
Operon
Sequence of genes responsible for synthesizing the enzymes needed for biosynthesis of a molecule. An operon is controlled by an operator gene and a repressor gene.
Organic compound
A compound containing carbon.

P

Passive immunity
Immunity acquired from receiving preformed antibodies.
Pathogen
Disease-causing organism.
Peptide
Two or more amino acids joined by a linkage called a peptide bond.
Phagocyte
A type of white blood cell that can ingest invading microorganisms and other foreign material. See also *Macrophage*.
Phenotype
Observable characteristics resulting from interaction between an organism's genetic makeup and the environment. Compare *Genotype*.
Photosynthesis
Conversion by plants of light energy into chemical energy, which is then used to support the plants' biological processes.
Phytoremediation
The use of plants to clean up pollution.
Plasma
The fluid (noncellular) fraction of blood.
Plasmapheresis
A technique used to separate useful factors from blood.
Plasmid
A small circular form of DNA that carries certain genes and is capable of replicating independently in a host cell.
Pluripotent cells
Having the capacity to become any kind of cell or tissue in the body. Embryonic stem cells and cells of the inner cell mass are pluripotent. Adult stem cells are multipotent. The mammalian embryo (blastocyst trophoblast plus inner cell mass) is totipotent because it can become an entire organism. Fully differentiated cells from many plants are totipotent.
Polyclonal
Derived from different types of cells.
Polymer
A long molecule of repeated subunits.
Polymerase
General term for enzymes that carry out the synthesis of nucleic acids.
Polymerase chain reaction (PCR)
A technique to amplify a target DNA sequence of nucleotides by several hundred thousandfold.
Polypeptide
Long chain of amino acids joined by peptide bonds.

Preclinical studies
Studies that test a drug on animals and in other nonhuman test systems. Safety information from such studies is used to support an investigational new drug application (IND).
Prokaryote
An organism (e.g., bacterium, virus, cyrobacterium) whose DNA is not enclosed within a nuclear membrane. Compare *Eukaryote*.
Promoter
A DNA sequence that is located in front of a gene and controls gene expression. Promoters are required for binding of RNA polymerase to initiate transcription.
Prophage
Phage nucleic acid that is incorporated into the host's chromosome but does not cause cell lysis.
Protein
A molecule composed of amino acids. There are many types of proteins, all carrying out a number of different functions essential for cell growth.
Protein A
A protein produced by the bacterium *Staphylococcus aureus* that specifically binds antibodies. It is useful in the purification of monoclonal antibodies.
Proteomics
Each cell produces thousands of proteins, each with a specific function. This collection of proteins in a cell is known as the proteome, and, unlike the genome, which is constant irrespective of cell type, the proteome varies from one cell type to the next. The science of proteomics attempts to identify the protein profile of each cell type, assess protein differences between healthy and diseased cells, and uncover not only a protein's specific function but also how it interacts with other proteins.
Protoplast
The cellular material that remains after the cell wall has been removed from plant and fungal cells.
Pure culture
In vitro growth of only one type of microorganism.

R

Radioimmunoassay (RIA)
A test combining radioisotopes and immunology to detect trace substances. Such tests are useful for studying antibody interactions with cell receptors, and can be developed into clinical diagnostics.
Rational drug design
Using the known three-dimensional structure of a molecule, usually a protein, to design a drug molecule that will bind to it. Usually viewed as an alternative to drug discovery through screening many molecules for biological activity.
Reagent
Substance used in a chemical reaction.
Recombinant DNA (rDNA)
The DNA formed by combining segments of DNA from two different sources.
Regeneration
Laboratory technique for forming a new plant from a clump of plant cells.
Regulatory gene
A gene that acts to control the protein-synthesizing activity of other genes.
Replication
Reproduction or duplication, as of an exact copy of a strand of DNA.
Replicon
A segment of DNA (e.g., chromosome or plasmid) that can replicate independently.
Repressor
A protein that binds to an operator adjacent to a structural gene, inhibiting transcription of that gene.
Restriction enzyme
An enzyme that breaks DNA in highly specific locations, creating gaps into which new genes can be inserted.

Restriction fragment length polymorphism (RFLP)
The variation in the length of DNA fragments produced by a restriction endonuclease that cuts at a polymorphic locus. This is a key tool in DNA fingerprinting and is based on the presence of different alleles in an individual. RFLP mapping is also used in plant breeding to see if a key trait such as disease resistance is inherited.
Reticuloendothelial system
The system of macrophages, which serves as an important defense system against disease.
Retrovirus
A virus that contains the enzyme reverse transcriptase. This enzyme converts the viral RNA into DNA, which can combine with the DNA of the host cell and produce more viral particles.
Rheology
Study of the flow of matter such as fermentation liquids.
Rhizobium
A class of microorganisms that converts atmospheric nitrogen into a form that plants can utilize for growth. Species of this microorganism grow symbiotically on the roots of certain legumes, such as peas, beans and alfalfa.
Ribonucleic acid (RNA)
A molecule similar to DNA that delivers DNA's genetic message to the cytoplasm of a cell where proteins are made.
Ribosome
A cellular component, containing protein and RNA, that is involved in protein synthesis.
RNA interference
A natural process used by organisms to block protein production.

S

Scale-up
Transition from small-scale production to production of large industrial quantities.
Selective medium
Nutrient material constituted such that it will support the growth of specific organisms while inhibiting the growth of others.
Sepsis
The presence in the blood or other tissues of pathogenic microorganisms or their toxins; the condition associated with such presence.
Sequencing
Decoding a strand of DNA or gene into the specific order of its nucleotides: adenine, cytosine, guanine and thymine. This analysis can be done manually or with automated equipment. Sequencing a gene can require analyzing an average of 40,000 nucleotides.
Serology
Study of blood serum and reactions between the antibodies and antigens therein.
Single-cell protein
Cells or protein extracts from microorganisms, grown in large quantities for use as protein supplements.
Somatic cells
Cells other than sex or germ cells.
Somatic cell gene therapy
Somatic cell gene therapy involves the insertion of genes into cells for therapeutic purposes; for example, to induce the treated cells to produce a protein that the body is missing. It does not affect genetic makeup of a patient's offspring and generally does not change all, or even most, cells in the recipient. Somatic cell gene therapy is only one way of applying the science of genomics to improve health care.
Splicing
The removal of introns and joining of exons to form a continuous coding sequence in RNA.
Stop codon
One of three codons in messenger RNA that signal the end of the amino acid chain in protein synthesis.

Structural gene
A gene that codes for a protein, such as an enzyme.
Substrate
Material acted on by an enzyme.
Suicide gene
A gene that codes for an antibiotic that can kill the host bacterial cell. It is genetically modified into the bacterium along with a molecular switch that is controlled by a nutrient in the environment. When the nutrient disappears, the suicide gene is switched on and the bacterium dies.
Suppressor gene
A gene that can reverse the effect of a mutation in other genes.
Systems biology
A hypothesis-driven field of research that creates predictive mathematical models of complex biological processes or organ systems.

T

Technology transfer
The process of transferring discoveries made by basic research institutions, such as universities and government laboratories, to the commercial sector for development into useful products and services.
Template
A molecule that serves as the pattern for synthesizing another molecule.
Terminator
Sequence of DNA bases that tells the RNA polymerase to stop synthesizing RNA.
Tertiary structure
The total three-dimensional shape of a protein that is essential to protein function.
Therapeutics
Compounds that are used to treat specific diseases or medical conditions.
Thymus
A lymphoid organ in the lower neck, the proper functioning of which in early life is necessary for development of the immune system.
Tissue culture
In vitro growth in nutrient medium of cells isolated from tissue.
Tissue plasminogen activator (tPA)
A protein produced in small amounts in the body that aids in dissolving blood clots.
T lymphocytes (T-cells)
White blood cells that are produced in the bone marrow but mature in the thymus. They are important in the body's defense against certain bacteria and fungi, help B lymphocytes make antibodies and help in the recognition and rejection of foreign tissues. T lymphocytes may also be important in the body's defense against cancers.
Toxin
A poisonous substance produced by certain microorganisms or plants.
Transcription
Synthesis of messenger (or any other) RNA on a DNA template.
Transdifferentiation
The process whereby a specialized cell de-differentiates and re-differentiates into a different cell type; or the process whereby an adult stem cell from a specific tissue type becomes a cell type from a very different tissue (for example a nerve stem cell differentiates into a kidney cell).
Transduction
Transfer of genetic material from one cell to another by means of a virus or phage vector.
Transfection
Infection of a cell with nucleic acid from a virus, resulting in replication of the complete virus.
Transfer RNA (tRNA)
RNA molecules that carry amino acids to sites on ribosomes where proteins are synthesized.
Transformation
Change in the genetic structure of an organism by the incorporation of foreign DNA.
Transgenic organism

An organism formed by the insertion of foreign genetic material into the germ line cells of organisms. Recombinant DNA techniques are commonly used to produce transgenic organisms.

Translation

Process by which the information on a messenger RNA molecule is used to direct the synthesis of a protein.

Transposon

A segment of DNA that can move around and be inserted at several sites in bacterial DNA or in a phage, thus alerting the host's DNA.

Tumor necrosis factors (TNF)

Rare proteins of the immune system that appear to destroy some types of tumor cells without affecting healthy cells.

V

Vaccine

A preparation that contains an antigen, consisting of whole disease-causing organisms (killed or weakened) or parts of such organisms, that is used to confer immunity against the disease that the organisms cause. Vaccine preparations can be natural, synthetic or derived by recombinant DNA technology.

Vector

The agent (e.g., plasmid or virus) used to carry new DNA into a cell.

Virion

An elementary viral particle consisting of genetic material and a protein covering.

Virology

Study of viruses.

Virulence

Ability to infect or cause disease.

Virus

A submicroscopic organism that contains genetic information but cannot reproduce itself. To replicate, it must invade another cell and use parts of that cell's reproductive machinery.

W

White blood cells

Leukocytes.

Wild type

The form of an organism that occurs most frequently in nature.

X

X-ray crystallography

An essential technique for determining the three-dimensional structure of biological molecules. This information aids in the discovery of products that will interact with the biological molecule.

Xenobiotics

Synthetic chemicals believed to be resistant to environmental degradation. A branch of biotechnology called bioremediation is seeking to develop biological methods to degrade such compounds.

Xenotransplantation

The transplantation of living organs, cells or tissues from animals into humans.

Y

Yeast

A general term for single-celled fungi that reproduce by budding. Some yeasts can ferment carbohydrates (starches and sugars) and thus are important in brewing and baking.

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